NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

September 4 - 5, 2024

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

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

Nevada State Board of Pharmacy

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

Date Posted: August 20, 2024

AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, September 4, 2024, at 9:00 am. The meeting will continue Thursday, September 5, 2024, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

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

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

Please Note:

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

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

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

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

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

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

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

◈ CONSENT AGENDA ◈

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

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

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

A. American Wound Care Pros, LLC – Fort Worth, TX

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

Background Check Not Required by Law.

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

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

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

B. Geron Corporation – Foster City, CA
C. Howmedica Osteonics Corporation – Mahwah, NJ
D. K2M, Inc – Leesburg, VA
E. Linde Inc – Phoenix, AZ
F. Mako Surgical Corporation – Weston, FL
G. Mobius Imaging, LLC – Shirley, MA
H. Stryker Corporation – Portage, MI
I. Stryker Corporation – Portage, MI
J. Stryker Corporation – Portage, MI
K. Stryker Corporation – Fremont, CA
L. Stryker Communications, Inc – Flower Mound, TX
M. Stryker Endoscopy, a Division of Stryker Corporation – San Jose, CA
N. TMJ Solutions, LLC – Ventura, CA
O. Tornier, Inc – Bloomington, MN
P. Welch Allyn, Inc – Skaneateles Falls, NY

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

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

Q. Quest Pharmaceuticals, Inc – Murray, KY
R. RxCrossroads 3PL LLC – Shepherdsville, KY

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

S. Advanced Accelerator Applications USA, Inc – San Diego, CA
T. Ajenat Pharmaceuticals, LLC – Tampa, FL
U. Alcon Vision, LLC – Fort Worth, TX
V. Azurity Pharmaceutical, Inc – Woburn, MA
W. Citigenix Regen, LLC – Novi, MI
X. ITF Therapeutics, LLC – Concord, MA
Y. Pangea Pharmaceuticals, LLC – Brielle, NJ

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

Z. Endeavor Distribution, LLC – Oklahoma City, OK

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

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

AA. Clean Earth of Alabama, Inc – Glencoe, AL
BB. DHL Supply Chain (USA) – Middletown, PA
CC. J & B Medical Supply, Co., Inc – Wixom, MI
DD. TS Pharm, Inc – Irvine, CA

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

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

EE. Instacare Pharmacy – Las Vegas, NV
FF. QHR Pharmacy – Las Vegas, NV

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

GG. Beaker Pharmacy – McKinney, TX
HH. Option Care – Salt Lake City, UT
II. Premier Pharmacy – San Antonio, TX
JJ. RLS (USA) Inc – Sacramento, CA
KK. Seven Cells – Stuart, FL
LL. Vios Compounding Pharmacy - MI
MM. Wedgewood Pharmacy LLC – Lexington, KY

NN. Wedgewood Pharmacy LLC – Swedesboro, NJ
OO. Wedgewood Village Pharmacy LLC – Scottsdale, AZ

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

PP. Access Therapy Center – Pittsburgh, PA
QQ. Chewy Pharmacy MC04, LLC – Ocala, FL
RR. Chewy Pharmacy DFW8, LLC – Dallas, TX
SS. Diabetes Supply Center of the Midlands, LLC – Omaha, NE
TT. GoGo Meds West – Scottsdale, AZ
UU. HomeFree Pharmacy Services – Indianapolis, IN
VV. ImprimisRx Nashville, LLC – Nashville, TN
WW. InjuryScripts – Jacksonville, FL
XX. Manatee Discount Pharmacy – Bradenton, FL
YY. NextRx Pharmacy – Columbia, MO
ZZ. PharmaCord – Louisville, KY
AAA. Physicians Preference Pharmacy International LLC – Katy, TX
BBB. Ridgeway Pharmacy Closed Door – Victor, MT
CCC. Valiant Compounding Pharmacy – Ypsilanti, MI

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

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

DDD. Christopher Tyler

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

◈ REGULAR AGENDA ◈

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

A.	Festus Ebonka	(19-012-CS-S)
B.	Smith's Pharmacy #350	(19-247-PH-S)
C.	Lolita Simon Caoile	(19-247-RPH-S)
D.	Walgreens Pharmacy #05479	(21-169-PH-S)
E.	Walgreens Pharmacy #02445	(21-169-PH-O)
F.	Grace Opulencia	(21-169-RPH-S)
G.	Sam Zand	(21-229-CS-A-S)
H.	CVS Pharmacy #9842	(22-200-PH-N)
I.	Anup Chabra	(22-200-RPH-N)
J.	Walgreens Pharmacy #3845	(22-366-PH-S)
K.	Yoojin Jeong	(22-366-RPH-S)

L.	American Wellness Pharmacy	(23-063-PH-S)
M.	Thomas Schotik	(23-063-RPH-S)
N.	David Lanzkowsky	(23-106-CS-A-S)
O.	William Baumgartl	(23-106-CS-B-S)
P.	Robert Feingold	(23-118-CS-S)
Q.	Jason Dazley	(23-266-CS-A-S)
R.	Joseph Palumbo	(23-266-CS-B-S)
S.	Matthew Dikin	(23-482-CS-S)
T.	Amazon Pharmacy #002	(24-102-PH-O)
U.	Matthew Okeke	(19-013-CS-S)
V.	CVS Pharmacy #6717	(20-133-PH-S)
W.	Negar Savafi	(20-133-RPH-S)
X.	Jones Feed and Tack	(21-064-S)
Y.	Angelina Bucu	(21-072-CS-S)
Z.	CVS Pharmacy #9842	(22-169-PH-N)
AA.	Candice Denham	(23-257-CS-S)
BB.	Tammara Sam Beeghly	(23-274-CS-S)
CC.	Walgreens Pharmacy #6424	(23-310-PH-S)
DD.	Sanette Severance	(23-310-RPH-S)
EE.	Nana Kufour	(23-341-CS-S)

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

   A. Heath DeHart

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

   A. Advantage Medical Supply, Inc – Mesquite, NV
   B. H-Blu Medical Supply, LLC – Reno, NV
   C. Maxcare Medical Equipment, LLC – Las Vegas, NV

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

   A. Alta Rose Surgery Center – Las Vegas, NV

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

   A. Diamond Specialty Pharmacy – Las Vegas, NV
   B. District Pharmacy – Las Vegas, NV
   C. Staywell Pharmacy – Las Vegas, NV
   D. Thrive Behavioral Hospital – Las Vegas, NV

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

A. OSRX, Inc. #2675 – Missoula, MT

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

    A. Belmar Pharmacy – Odessa, FL

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

    A. Geodis Logistics LLC – Rincon, GA – Background Check Not Required in compliance with NAC 639.593(6)(d)

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

    A. Alcami Carolinas Corporation – Reno, NV - Background Check Not Required in compliance with NAC 639.593(6)(d)
    B. DESS-USA, Inc – Reno, NV – Background Check Not Required in compliance with NAC 639.593(6)(d)

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

    A. Eyenovia, Inc – Reno NV

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

    A. Sean Levins

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

    A. Braden Uppinhouse

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

    A. Kristin Hestdalen
    B. Raymond Trangredi

18. Approval of Pharmacy Technician in Training Application - Appearance **(FOR POSSIBLE ACTION)**

    A. Nicole Brooks

◈ PUBLIC HEARING ◈

Thursday, September 5, 2024 – 9:00 am

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

    A. **Amendment to Nevada Administrative Code (NAC) 639.** The proposed amendments clarifies record keeping requirements of counseling by a pharmacy. (LCB File No. R085-24)

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

21. Executive Secretary Report:

    A. Financial Report
    B. Issuance of Temporary Licenses and Registrations
    C. Change of Address Business List
    D. Meetings with Other Health Care Regulatory Boards
    E. Licensing Activities Report
    F. Citations & Fines issued pursuant to NRS 632.2895
    G. Legislative Update
    H. 2025 Nevada Board of Pharmacy Yearly Calendar

22. Date and Location of Next Scheduled Board Meeting:

    October 16-17, 2024 – Las Vegas, NV

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

24. Adjournment

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

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

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

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

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NEVADA STATE BOARD OF PHARMACY

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

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

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

MINUTES

July 17-18, 2024

BOARD MEETING

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

Element Reno Experience District
2030 Element Ln.
Reno, NV 89502

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

Board Members Present:

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

Board Staff Present:

David Wuest	Yenh Long	Gregory Zunino	Brett Kandt
Darlene Nases	Mui Lee	Erin Miller	Jessette Phaynarikone
Joe Dodge	John Castaldo	Todd Weiss	

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

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

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

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

2. Public Comment July 17, 2024, 9:22 AM

Ken Kunke, Nevada Pharmacy Alliance, shared that Nevada Pharmacy Alliance is holding their annual meeting in Reno on September 20-21, 2024 at the Silver Legacy in Reno, NV and more information can be found at their website.

◈ CONSENT AGENDA ◈

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

3. Approval of the May 29-30, 2024, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board Action:

Motion: Wayne Mitchell moved to approve the May 29-30, 2024, Board Meeting Minutes.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. Acelis Connected Health Supplies – Gainesville, FL
B. BioHorizon Medical, Inc – Torrance, CA
C. Horizon Wound Care, LLC – Fort Worth, TX

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

Background Check Not Required by Law.

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

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D. Zoll Medical Corp – North Billerica, MA

4.2.2 Manufacturer (NAC 639.593(6)(d))

E. 3B Medical Inc – Sarasota, FL
F. Apotex Corp. – Plainfield IN
G. Bionpharma, Inc – Princeton, NJ
H. Hager Worldwide, Inc – Hickory, NC
I. Invenio Alternate Care Solutions, LLC – Peachtree, GA
J. Legacy Pharma USA, Inc – Scottsdale, AZ
K. Metro Park Warehouses, LLC – Kansas City, MO
L. Philips RS North America, LLC – Morrysville, PA
M. ResMed Corporation – Moreno Valley, CA
N. ResMed Corporation – Litha Springs, GA
O. TriMed, Inc – Valencia, CA
P. Spectranetics LLC – Colorado Springs, CO
Q. Caplin Steriles USA Inc. – Hamilton, NJ
R. Slayback Pharma, LLC – Princeton, NJ
S. Zoll Medical Corp. – Chelmsford, MA
T. Zoll Medical Corp. – Deerfield, WI

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

U. Hayes Handpiece Franchises, Inc – Lenexa, KS
V. Merus US, Inc – Cambridge, MA
W. Neogen Corporation – Mt. Sterling, KY

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

X. Tolmar, Inc. – Windsor, CO
Y. Ritedose Pharmaceuticals, LLC – Columbia, SC

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

Z. Health Coalition, LLC – Doral, FL

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

AA. Glaukos Corporation – Aliso Viejo, CA
BB. Janssen Pharmaceuticals, Inc. – Titusville, NJ

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

CC. McKesson Medical-Surgical Inc – Kent, WA

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

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

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

DD. 986 Pharmacy #8026 – Las Vegas, NV
EE. Spring Mountain Treatment Center – Las Vegas, NV FF. Northwest Specialty Pharmacy – Reno, NV

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

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

GG. VitaScripts – Tampa, FL
HH. AHF Pharmacy – Gardena, CA
II. Vanscoy Rare Pharmacy – Pittsburgh, PA
JJ. Palmetto Pharm – Mount Pleasant, SC

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

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

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

David Wuest noted that Item 4E has been removed from the Consent Agenda and will be seen at a future Board Meeting.

Krystal Freitas recused herself from Agenda Items 4EE and 4FF due to her employment.

Board Action:

Motion: Wayne Mitchell moved to approve the Consent Agenda with exceptions of Agenda Items 4EE and 4FF.

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Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: President Park moved to approve the Consent Agenda Items 4EE and 4FF.

Second: Wayne Mitchell

Action: Passed unanimously (Freitas recused).

◈ REGULAR AGENDA ◈

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

B. Ricardo Gonzalez (22-247-CS-B-N)

Ed Lemons appeared as counsel on behalf of Ricardo Gonzalez.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that the respondent failed to query a patient report from the PMP database prior to issuing two separate controlled substance prescriptions. In addition, Dr. Gonzalez failed to query and review for accuracy his MyRx prescriber activity report at least once every six months, as required by Nevada Law.

Mr. Kandt presented a proposed Stipulation and Order for Case No. 22-247-CS-B-N for the Board's consideration.

The proposed stipulated penalties for Dr. Gonzalez Certificate of Registration No. CS11387 are the following: 1) pay $2,000 fine for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, both due by September 1, 2024.

Board discussion ensued.

Board Action:

Motion: Kystal Freitas moved to approve the Stipulation and Order for Ricardo Gonzalez as presented by Mr. Kandt.

Second: Wayne Mitchell

Action: Passed unanimously.

J. Maurice Vargas (21-086-CS-N)

Jessica Gandy, Esq. appeared as counsel on behalf of Maurice Vargas.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Mr. Vargas alleging Mr. Vargas only queried nine times between January 1, 2018, to September 18, 2023, where he wrote at least 890 prescriptions for at least 650 unique patients.

Mr. Zunino presented the proposed Stipulation and Order for Case No. 21-086-CS-N for the Board's consideration.

The proposed stipulated penalties for Mr. Vargas Certificate of Registration No. CS15506 are the following: 1) pay a $5,000 fine for the violations; and 3) pay $1,000 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to approve the Stipulation and Order for Maurice Vargas as presented by Mr. Zunino.

Second: Krystal Freitas

Action: Passed unanimously.

E. CVS Pharmacy #4691 (22-503-PH-N)
F. Ayman Jalloul (23-503-RPH-N)

Brian Convery appeared as a representative on behalf of CVS Pharmacy #4691 and Ayman Jalloul appeared and both were sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging an error in a prescription that resulted in a negative outcome to the patient. Mr. Kandt presented a proposed Stipulation and Order for Case No. 22-503-PH-NN and Case No. 23-503-RPH-N for the Board's consideration.

The proposed stipulated penalties for CVS Pharmacy #4691, Pharmacy License No. PH02471, are the following: 1) pay $2,000 fine for the violations; and 2) pay $1,000 to

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partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, both due by September 1, 2024.

The proposed stipulated penalties for Mr. Jalloul, Certificate of Registration No. 23280, are the following: 1) pay $1,000 fine for the allegations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, both due by September 1, 2024.

Board discussion ensued.

Board Action:

Motion: Gener Tejero moved to approve the Stipulation and Orders for CVS Pharmacy # 4691 and Ayman Jalloul for as presented by Mr. Kandt.

Second: Adam Porath

Action: Passed unanimously (Jacobo recused).

H.	CVS Pharmacy #9840	(23-433-PH-N)
I.	Deisy Serrano Moreno	(23-433-RPH-N)

Brian Convery appeared as a representative on behalf of CVS Pharmacy #9840 and was still sworn in from a prior case. Deisy Serrano Moreno appeared and was sworn in prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging Ms. Serrano Moreno failed to review patient M.C.'s record prior to counseling or reviewed the patient's profile in a manner that was inadequate to provide the patient proper counseling

Mr. Zunino presented the proposed Stipulation and Order for Case No. 23-433-PH-N and 23-433-RPH-N for the Board's consideration.

The proposed stipulated penalties for CVS Pharmacy #9840, Pharmacy License No. PH01366, are the following: 1) pay $2,000 fine for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

The proposed stipulated penalties for Ms. Serrano Moreno, Certificate of Registration No. 14845, are the following: 1) pay $1,000 fine for the allegations; 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter; and 3) complete 4 additional CEU credits on the topic of counseling.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Orders for CVS Pharmacy #9840, and Deisy Serrano Moreno as presented by Mr. Zunino.

Second: Krystal Freitas

Action: Passed unanimously.

8. Discussion and possible action to vacate Findings of Fact, Conclusions of Law and Order entered May 30, 2024, and grant a rehearing in Nevada State Board of Pharmacy v. Brenda Vaknin, RPH, Case No. 19-134-RPH-S. **(FOR POSSIBLE ACTION)**

Brenda Vaknin appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Vaknin requested that the Board vacate the Findings of Fact, Conclusions of Law and Order entered upon default on May 29, 2024, and grant a rehearing on this matter in which she was disciplined for an error in a prescription that resulted in a negative outcome to the patient and failing to counsel patient, and as managing pharmacist for the pharmacy's failure to provide medication counseling to patients and maintain documentation of medication counseling.

The Board questioned Ms. Vaknin regarding what had occurred when she failed to appear for the May 29, 2024, hearing.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, gave a brief overview of the charges in the case.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to deny the request to vacate the Findings of Fact, Conclusions of Law and Order and not grant a rehearing on this matter.

Second: President Park

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

Action: Motion carries (Jacobo recused).

7. Nazanin Kazeminy (23-140-RPH-N)

Aaron Fricke, Esq. appeared as counsel for Ms. Kazeminy.

Nazanin Kazeminy appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case against where Ms. Kazeminy was found guilty of making a false record of COVID-19 vaccinations reportedly administered to her former boyfriend. Ms. Kazeminy is requesting a reconsideration of the discipline imposed.

Mr. Zunino presented the proposed Stipulation and Order for Case No. 23-140-RPH-N for the Board's consideration.

The proposed stipulated penalties for Ms. Kazeminy, Certificate of Registration No. 20034, are the following: 1) Certificate of Registration No. 20034 is revoked; however, the revocation is stayed and Ms. Kazeminy is placed on probation for a period of five years; 2) pay a $5,000 fine for the violations; 3) pay $8,406.29 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter; 4) as a condition of probation, Ms. Kazeminy's license shall be suspended until January 1, 2025; and 5) as a condition of probation, Ms. Kazeminy must complete a 22-hour "Ethics and Professionalism" bootcamp course within 120 days of the Order.

Mr. Fricke spoke on behalf of the respondent and notified the Board that they would like to go into closed session.

Board discussion ensued.

Board Action:

Motion: President Park moved to go into closed session.

Second: Krystal Freitas

Action: Passed unanimously (Jacobo recused).

Board Action:

Motion: President Park moved to go into open session.

Second: Krystal Freitas

Action: Passed unanimously (Jacobo recused).

Wayne Mitchell was excused from the meeting at 11:37AM and returned at 11:38AM.

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Gener Tejero requested a modification to provision 8D in the proposed Stipulation and Order by increasing the suspension to one (1) year until April 18, 2025.

Ms. Kazeminy agreed to the revised stipulation.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the amended Stipulation and Order for Nazanin Kazeminy with amendments to increase the suspension to engage in the practice of pharmacy until April 18, 2025.

Second: Adam Porath

Action: Passed unanimously (Jacobo recused).

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

G. Candice Denham (23-257-CS-S)

This matter was continued to a future Board meeting.

26. Executive Secretary Report:

A. Financial Report

David Wuest, Executive Secretary of the Nevada Board of Pharmacy, shared that there is no financial report. He would not be presenting any fiscal numbers at this time as they will need until August to close those financials out.

A. Karri Burgner (22-247-CS-A-N)

Karri Burgner appeared via zoom and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that the respondent failed to query patient utilization reports in the PMP and issued 22 separate controlled substance prescriptions. In addition, Respondent Burgner failed to query and review for accuracy her MyRx prescriber activity report at least once every six months, as required by Nevada Law.

Mr. Kandt presented a proposed Stipulation and Order for Case No. 22-247-CS-A-N for the Board's consideration.

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The proposed stipulated penalties for Ms. Burgner, Certificate of Registration No. CS15148, are the following: 1) pay a $2,000 fine for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, both due by September 1, 2024.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Karri Burgner.

Second: Krystal Freitas

Action: Passed unanimously.

D. Nerissa Aguas (23-456-RPH-N)

Adam Porath recused himself from this matter due to Ms. Aguas is currently an employee at his place of employment.

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

Kevin Murphy, Esq. appeared as counsel for Nerissa Aguas.

Nerissa Aguas appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging Ms. Aguas failed to review the actual physical contents of two prescriptions during final product verification, and is responsible for errors in the prescriptions.

Mr. Kandt presented the proposed Stipulation and Order for Case No. 23-456-RPH-N for the Board's consideration.

The proposed stipulated penalty for Ms. Aguas, Certificate of Registration No. 14977, is to pay a fine of $500 for the violations by September 1, 2024.

Board discussion ensued.

Board Action:

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

Second: Richard Tomasso

Action: Passed unanimously (Porath and Jacobo recused).

C. CVS Pharmacy #8806 (23-456-PH-N)

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

Gener Tejero stated that he has a professional relationship with Bill Stilling but can participate fairly and without bias.

Brian Convery appeared as a representative of CVS Pharmacy #8806 and is still sworn in from a previous matter.

William Stilling, Esq. appeared as counsel on behalf of CVS Pharmacy #8806.

Todd Weiss, Deputy Attorney General for the Attorney's General Office, questioned Mr. Stilling on if he has an issue with Adam Porath participating in this matter as he recused himself from the Nerissa Aguas hearing.

Mr. Stilling had no issue with Adam Porath participating in this matter.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against CVS Pharmacy #8806, as pharmacy owner, is responsible for the acts of Ms. Aguas failing to review the actual physical contents of two prescriptions during final product verification resulting in errors in the prescriptions.

Mr. Kandt and opposing counsel stipulated, on the record, to amending paragraphs 9 and 10 in the Notice of Intended Action and Accusation to change the Nevada Law citation to NAC 639.945(3).

Mr. Kandt gave his opening statement and noted that the pharmacy technician, Giovanni Bartice, could not be located and subpoenaed for the hearing.

Mr. Stilling gave his opening statement, presenting that CVS Pharmacy #8806 is vicariously liable as the pharmacy/pharmacy owner.

Mr. Kandt called Nerissa Aguas as a witness.

Mr. Stilling objected to Ms. Aguas giving testimony on the basis that it was irrelevant.

President Park overruled the objection.

Nerissa Aguas appeared, and President Park reminded Ms. Aguas that she was still sworn in from a prior case.

Mr. Kandt questioned Ms. Aguas and had her read her written statement from the

investigation into the record and requested that it be entered into evidence as Exhibit 1.

Mr. Stilling objected to using the old, black and white photographs from Exhibit 1 from being entered into record.

President Park overruled the objection and admitted Exhibit 1 into the record.

Board staff verified that Ms. Aguas' counsel, Kevin Murphy, was made aware of the color photos being presented as proposed Exhibits 2 and 3.

Mr. Kandt presented a color photocopy of the first prescription to Ms. Aguas and upon authentication, requested that is be entered into record as Exhibit 2.

President Park admitted Exhibit 2 into the record.

Mr. Kandt presented a second color photocopy of the second prescription to Ms. Aguas and, upon authentication, requested it to entered into the record as Exhibit 3.

Mr. Stilling objected to the photos being entered.

President Park overruled the objection and admitted Exhibit 3 into the record.

Mr. Kandt asked Ms. Aguas to explain the process of the virtual verification workflow when she was employed by CVS Pharmacy.

Mr. Stilling re-crossed Ms. Aguas.

The Board questioned Ms. Aguas on her testimony.

Mr. Stilling called Joseph Lavino, Pharmacist and Senior Legal Counsel at CVS Pharmacy, as a witness.

Joseph Lavino appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Stilling questioned Mr. Lavino on the virtual verification process within CVS and what was presented to the Board regarding virtual verification process.

Mr. Lavino answered Mr. Stillings questions.

Mr. Stilling presented proposed Exhibit 4 to Mr. Lavino and asked him to explain what is included in the potential exhibit.

Mr. Stilling requested President Park admit Exhibit 4, overview of CVS enhancements on the virtual verification workflow, into record.

DRAFT

Mr. Kandt objected to Mr. Stilling's continued questioning and testimony offered on the updates to the system that CVS has completed since this incident took place as irrelevant.

President Park sustained the objection.

Mr. Stilling continued to question Mr. Lavino.

Mr. Kandt had no questions for the witness and cautioned the Board to only ask questions that pertain to this case regarding the two misfilled prescriptions.

The Board questioned Mr. Lavino on his testimony.

Mr. Stilling called Mark Goven, Pharmacist and District Support Pharmacy Leader for CVS, as a witness.

Dr. Goven appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Kandt questioned Mr. Stilling if this witness will answer questions specifically pertaining to this store where the misfills occurred.

Dr. Goven stated that he was part of the training for CVS Pharmacy #8806 in this case.

Mr. Kandt questioned Dr. Goven.

Mr. Stilling recrossed.

The Board questioned Dr. Goven on his testimony.

Mr. Stilling called Jodi Lewis, Pharmacist and District Leader for CVS Pharmacy, as a witness.

President Park disclosed that she is familiar with Jodi Lewis but can participate in this matter fairly and without bias.

Mr. Stilling questioned Ms. Lewis on her background and what steps occur to fix an error by a pharmacist that is found.

Mr. Kandt objected to Mr. Stillings questioning of Ms. Lewis as irrelevant.

President Park sustained the objection.

Board discussion ensued.

Mr. Kandt gave his closing argument on this case.

DRAFT

Mr. Stilling gave his closing argument on this case.

Mr. Kandt requested the Board to make the Findings of Fact consistent with paragraphs 1-5 of the Accusation.

Board discussion ensued.

Board Action:

Motion: President Park moved to make the Findings of Fact consistent with paragraphs 1-5 of the Accusation.

Second: Adam Porath

Action: Passed unanimously (Jacobo recused).

Mr. Kandt requested the Board to make the Conclusions of Law consistent with paragraphs 6-10 of the Accusation and to find CVS Pharmacy #8806 guilty on Count One.

Mr. Stilling objected to any paragraphs that do not name CVS Pharmacy #8806 in the Accusation.

Mr. Kandt commented that CVS is responsible for the acts of all its employees.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to make the Conclusions of Law consistent with paragraphs 6-10 of the Accusation and find CVS Pharmacy #8806 guilty on Count One.

Second: President Park

Action: Passed unanimously (Jacobo recused).

Mr. Kandt presented a Memorandum of Fees and Costs be entered into record as Exhibit 5.

President Park admitted as Exhibit 5.

Mr. Kandt requested that the Board find the attorney's fees and costs in the amount of $4,787.82 were reasonable, necessary, and actually incurred.

DRAFT

Board Action:

Motion: President Park moved to award the attorney's fees and costs of $4,787.82 on the basis that they were reasonable, necessary, and actually incurred.

Second: Wayne Mitchell

Action: Passed unanimously (Jacobo recused).

Mr. Kandt proposed the following discipline: the Board award the attorney's fees and costs of the $4,787.82 and assess a fine against CVS Pharmacy #8806 at their discretion.

Board discussion ensued

Board Action:

Motion: President Park moved to impose the following penalties on CVS Pharmacy #8806 License No. PH00640: 1) pay a $5,000 fine for the violations; and 2) pay $4,782.82 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter by September 1, 2024, effective immediately.

Second: Krystal Freitas

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

Action: Motion carries (Jacobo recused).

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

A. Kylie Sondermann (23-167-A-N)

This matter was withdrawn.

B. Ronald Burnett (23-342-PR-N)

This matter was withdrawn.

Public Comment July 17, 2024, at 5:05PM.

Kevin Murphy, Esq. appreciates the Board's time today.

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

DRAFT

Board Members Present:

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

Board Staff Present:

David Wuest	Yenh Long	Gregory Zunino	Brett Kandt
Darlene Nases	Mui Lee	Erin Miller	Jessette Phaynarikone
Joe Dodge	John Castaldo		

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

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

Call to Order and Roll Call – Establishment of Quorum

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

Public Comment July 18, 2024, 9:00 AM

Carla Nye, a community pharmacist, shared how the proposed regulation will create a larger workload for pharmacists. She believes the regulation would have a counterproductive outcome. Pharmacy Technicians wouldn't be able to help and will increase workloads and stress for pharmacists. She posed questions of how it will look in certain instances during her workflow each day.

Ken Kunke, NV Pharmacy Alliance, shared that NV Pharmacy Alliance is holding their annual meeting in Reno on September 20-21 at the Silver Legacy in Reno, NV and more information can be found on their website.

Jade Jacobo joined the meeting at 9:20AM.

◈ WORKSHOP ◈

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

    A. Amendment to Nevada Administrative Code NAC 639.748. The proposed amendments revise the requirements concerning the documentation an employee of a pharmacy must obtain from a person before dispensing a

DRAFT

controlled substance pursuant to a lawful prescription to the person. **(FOR POSSIBLE ACTION)**

Yenh Long, Deputy Secretary for Nevada State Board of Pharmacy, presented the background of the regulation and gave an overview of the proposed amendment that would be implemented. She also commented that they received a written letter of support from practitioners on this proposed regulation.

President Park opened the floor for public comment.

Kate Jessup, a nurse practitioner, requested the proposed amendments based on her encounters of certain group of patients that don't have an updated license (i.e. recently incarcerated or unhoused) which lead to the inability to get proper medication for an opioid disorder. She shared an example of how removing a barrier like this can help those not fall back into opioid usage.

Liz McMenamin, Retail Association of Nevada, stated that they are in support of this amendment. She appreciated that the language would allow the pharmacist to make the final determination, which she believed is a choice that pharmacists should have. Hoped that in the future, pharmacists can also prescribe opioid disorder medications for those that need it.

President Park closed the period for public comment.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Amendment to Nevada Administrative Code NAC 639.748.

Second: Adam Porath

Action: Passed unanimously.

B. Amendment to Nevada Administrative Code (NAC) 639. The proposed amendments clarify what it means to verify or perform verification of a prescription in a retail community pharmacy.

Yenh Long, Deputy Secretary for Nevada State Board of Pharmacy, presented the background of the proposed regulation and gave an overview of the amendments that would be implemented in each section.

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

President Park opened the floor for public comment.

DRAFT

Becky Richards, Pharmacist, commented that she is concerned with proposed regulation. Her interpretation of the proposed regulation is that the prescription verification process can no longer be done by shared central fill services. In addition, any verification in the prescription processing by a pharmaceutical technician needs to be verified by the supervising pharmacist which means that every aspect of filling a prescription has been done in that pharmacy. These proposed changes will cause more work and stress to the pharmacist by taking away the help and decrease the time that they have with their patients. She is not in favor of the proposed regulation

Victoria Kroeger, Pharmacist and Walgreen's Manager, commented that the use of automation, split verification, and centralized services, and virtual verification will reduce error rates and help pharmacist focus on patients physically present in the pharmacy. Centralized pharmacy pharmacists were responsible for over 50% less data review and DUR events than traditional pharmacist. She does not know why the Board would eliminate the safer workload shared technologies and processes that support pharmacies. The proposed regulation changes would double the work being completed in the pharmacies and eliminate the ability to properly support pharmacists, and it shows a clear bias towards retail community pharmacies compared to other pharmacy settings. She is not in favor of the proposed regulation as it will reduce the workload for pharmacist and improve their ability to direct patient care.

Jenna Cherchio, Pharmacist and Director of Pharmacy Operations for CVS Health commented the proposed regulation would be reverting pharmacist to a 14-step manual product verification process which would have them focus on non-clinical activities. Also, it would lose the ability to use these images to further safety innovation and the development of future innovation that would help pharmacist feel confident in what they are dispensing to customers. Virtual verification is a building block to address staffing concerns, and their program of Air Support can act as back up for pharmacists when needed, provide the support pharmacist need, and allows pharmacist to focus on patient care. She is not in favor or the proposed regulation as it will not allow the pharmacies to use the tools that are needed to address the concerns that are out there.

Eliscia Giampapa, Pharmacist, commented that removing remote health services will not improve work conditions. She wants to ensure that she has the opportunity to counsel patients and work with doctors directly, and the proposed regulation will hinder the time and services provided to patients if pharmacists lose the help of centralized services. She is not in favor of the proposed regulation as the impact that it will have on pharmacists that they want to assist and patients seeking their medical care.

Mark Johnston, CVS Health representative, referenced several publications which suggested the following improvements to medication practice in community pharmacies: 1) they replace old technology with new technology; 2) preventing medication errors in pharmacies the solution is automation or computerization; 3) to deflect distractions and intercept interruptions the solution is technology; and 4) the Board of Pharmacies

review, adopt, and update shared service laws. He is not in favor of the proposed regulation as it increases workload in pharmacies and will eliminate shared services.

Nichole Baker, community Pharmacist, is concerned that the proposed regulation may effect pharmacists' ability to provide safe patient care and will increase workloads at pharmacies. She suggests that we live in a time where we need to embrace technology especially technology that has been proven to reduce the risk of errors. She is not in favor of the proposed regulation.

Joseph Lavino, Senior Legal Counsel for CVS Health, requested the Board not to approve the proposed regulation as it is bad for patient safety, bad for business, and bad for the practice of pharmacy. He stated the Nevada Board of Pharmacy mission statement and presented data evidence that supports CVS virtual verification workflow as on average 20% safer than a pharmacist manually manipulating drug products to perform a prescription verification. This proposed regulation will eliminate shared services in pharmacies which raises the risks of errors. The Board is proposing to take away tools to make workplace conditions better and to take away technology and innovation to drive patient safety. He is not in favor of the proposed regulation.

Cassandra Fifield, Pharmacist technician with CVS, shared that she believed that eliminating virtual verification would heavily impact both her pharmacy and community pharmacies. She believed that with the proper training on virtual verification, it would reduce the chances of error. She stated that virtual verification allows for a cleaner workspace within the pharmacy and alleviates the workload of pharmacists available to counsel patients. She suggested that adding a picture of the pills inside the bottle to virtual verification process could help in reducing errors as discussion moves forward.

Jolene Blaine, CVS pharmacist, shared her direct experience that occurred when her two technicians called out. She stated that with virtual verification and air support, she was able to complete her high-volume workload even after needing to review how to use a blood pressure machine with a patient at the pharmacy over a ten-minute conversation, and complete seven immunizations that came in. She would like to find a solution instead of getting rid of these programs altogether and suggested that taking a second picture of the pills in the bottle during virtual verification could be helpful.

Liz McMenamin, Retail Association of Nevada, believed that this will impact every community pharmacy, and only community pharmacies. She believed this is moving backwards with the technology that has already been implemented in pharmacies across the state, unlike many other states. She is hoping to continue the conversation with Board staff as they move forward.
President Park closed the period for public comment.

Dave Wuest, Executive Secretary for the Nevada State Board of Pharmacy, commented that this is an industry wide amendment, not specifically for community pharmacies. He would like to continue the discussion and hoped to see data that was offered to him previously, but it would be best to bring data to the table for all those involved in the

discussion. He also shared that some hospitals do use cameras for verification, but not in the same way or for the same reasoning that virtual verification is being used in other types of pharmacies. He wants to work with the industry and believes there is a path to this industry-wide issue.

Yenh Long, Deputy Secretary for the Nevada Board of Pharmacy, stated that the intent of the regulation is to make sure someone is doing a final check prior to giving it to the patient, which will add a layer of protection for our patients since the Nevada Board of Pharmacy does receive a large amount of misfill cases where the pharmacist involved was utilizing either air support or virtual verification. She stated that the amendments are not meant to kill the ability to use shared services, but simply an added layer of protection to make sure that the correct medication is in the correct bottle for patients.

Board discussion ensued.

This item has been tabled and will be brought back to the Board.

Jade Jacobo left the meeting at 11:05AM.

◈ PUBLIC HEARING ◈

24. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(3) **(FOR POSSIBLE ACTION)**

    A. Amendment to Nevada Administrative Code (NAC) 639: The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standards. (LCB File No. R053-24)

David Wuest, Executive Secretary of the Nevada State Board of Pharmacy, presented background on the proposed public hearing item.

President Park opened up the floor for public comment.

Chad Baker, Senior Vice President of Government Relations at FLAVORx, applauded the Board for the pragmatic language around flavoring and compounding and is in favor of the proposed language. He believes that this change establishes sensible guardrails to protect the safety of the public, while also improving medication compliance.

Liz McMenamin, Retail Association of Nevada, appeared and was sworn in by President Park prior to offering testimony. She stated that she appreciated the Board's understanding of the industry need in flavoring and is in favor of the proposed language.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to adopt LCB File No. R053-24 as written and clarify with LCB to confirm the stricken language in LCB File No. R053.24I was actually repealed and amending to strike from Line 3 of Section 2 for human consumption.

Second: Krystal Freitas

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

Action: Motion carries.

Richard Tomasso was excused from the meeting at 11:35AM.

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

    A. Vitti Labs, Inc. – Liberty, MO – Background Check Not Required in compliance with NAC 639.593(6)(d)

Bill Stilling appeared as counsel on behalf of Vitti Labs, Inc.

Phillip Vitti, Owner, and Rick Sterling, Company Representative, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Richard Tomasso returned to the meeting at 11:40AM.

David Wuest, Executive Secretary for the Nevada State Board of Pharmacy, gave a brief overview of the wholesaler application and explained the unique product that they sell.

Mr. Vitti and Mr. Sterling explained their business model and background on the FDA warning letter that Vitti Labs received and rectified.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve Out-of-State Wholesaler License for Vitti Labs, LLC.

Second: Adam Porath

Action: Passed unanimously.

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

    E. Mail-Meds Clinical Pharmacy – Las Vegas, NV

Hansil Kalaria, Chief Pharmacy Officer, and Quynh Pham, Pharmacy Manager, both appeared and were sworn in by President Park prior to answering questions and offering testimony.

President Park disclosed that she familiar with Ms. Pham but can participate in this matter fairly and without bias.

Brett Kandt, General Counsel for the Nevada State Board of Pharmacy, gave a brief overview of the pharmacy application and questioned why they want to be in Nevada after operating solely in Florida prior.

Board discussion ensued.

Board Action:

Motion: Gener Tejero moved to approve the Nevada Pharmacy License for Mail-Meds Clinical Pharmacy.

Second: Krystal Freitas

Action: Passed unanimously.

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

    A. Seven Hills Pharmacy – Sharronville, OH

Chris Spitzer (Pharmacist in Charge), Quynh Do (Senior Director of Pharmacy Practice), and Mark Wagner (outside counsel) appeared and were sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for the NVBOP, gave a brief overview of the application and explained what occurred throughout the process of their application and what they have implemented to make sure they are following Nevada law.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Out-of-State Pharmacy License for Seven Hills Pharmacy with the conditions that they are not dispensing any

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controlled substances before notifying the Board and to secure a $100,000 Surety Bond in the name of Nevada Board of Pharmacy.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. ASPN Pharmacies 4, LLC – Las Vegas

Robert Anderson (Chief Financial Officer), Div Patel (Director of Pharmacy Operations), Michael Rabinowitz (Pharmacist in Charge), Maree Kiledjian (Senior Clinical Director for Patient Access), and Ami Patel (Vice President of Health Operations), appeared and were sworn in by President Park prior to answering questions and offering testimony.

President Park and Krystal Freitas disclosed that they are both familiar with Desiree Roth but can participate in this matter fairly and without bias.

David Wuest, Executive Secretary of NVBOP, gave a brief overview of the pharmacy application and what occurred at a meeting Board staff held with ASPN Pharmacies 4, LLC.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Out-of-State Pharmacy License for ASPN Pharmacies 4, LLC.

Second: Adam Porath

Action: Passed unanimously.

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

C. Independence Drug – Elko, NV

Camerin Passey, Owner and Pharmacist, and Brittani Passey, Owner and Chief Marketing Officer, appeared and were sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary of Nevada Board of Pharmacy, gave a brief overview of the application and Mr. Passey's past work history.

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

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Pharmacy License for Independence Drug pending a favorable inspection.

Second: Wayne Mitchell

Action: Passed unanimously.

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

F. Royal Ambulance Inc – Black Rock City, NV

John Rey Hassan, Chief Administrative Officer and in-house Counsel, and Ken Fernandes, President and CEO of Drug Regime Review Clinical Consultants, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Gener Tejero disclosed that he is familiar with Ken Fernandes but can participate in this matter fairly and without bias.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave an overview of the application and explained that they are providing medical care at Burning Man. Mr. Wuest questioned the applicants on what the pharmacy will look like and stated that Board staff will share past inspections with them as they are setting up.

Mr. Fernandes answered questions to the Board's satisfaction

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Pharmacy License for Royal Ambulance Inc.

Second: Adam Porath

Action: Passed unanimously.

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

A. Whole Gas Technologies, Inc – Reno, NV – Background Check Not Required in compliance with NAC 639.593(6)(d)

James Donohue (Owner and Director of Sales and Marketing), William Tim Grohs (Owner and President), and Renato Garcia (Owner and Quality Control) appeared and were sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave a brief background of the wholesaler application and questioned the applicants on how they started their business.

The Board questioned on owner's work background.

Mr. Grohs, Mr. Donohus, and Mr. Garcia answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Gener Tejero moved to approve the Nevada Wholesaler License for Whole Gas Technologies, Inc pending a favorable inspection.

Second: Adam Porath

Action: Passed unanimously.

9. Application for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6942) – Appearance **(FOR POSSIBLE ACTION)**

B. Tens Unlimited, LLC – Las Vegas, NV

Doris Edmiston, Owner, appeared and was sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave a brief background of the application and clarified with the applicant that she needs to update the administrator once she hires staff and designates an employee. Mr. Wuest questioned what made her want to open this business and her past work experience

Board discussion ensued.

Board Action:

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Motion: Adam Porath moved to approve the Nevada Medical, Devices, Equipment and Gases License for Tens Unlimited, LLC, pending a favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

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

D. Las Vegas Community Pharmacy – Las Vegas, NV

Natalie Nguyen, Managing Pharmacist, and Ali Macintosh, President, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt, General Counsel for NVBOP, gave a brief overview of the change of ownership application.

The Board questioned Mr. Macintosh about his background, why he started this business, and if any policies and procedures have been changed with the change of ownership.

Mr. Macintosh and Ms. Nguyen answered questions to the Board's satisfaction. Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve Nevada Pharmacy License for Las Vegas Community Pharmacy.

Second: Krystal Freitas

Action: Passed unanimously.

22. Election of President and Treasurer pursuant to NRS 639.040 - **(FOR POSSIBLE ACTION)**

The Board members voted to elect the President and Treasurer.

Board discussion ensued.

Board Action:

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Motion: Richard Tomasso moved to reappoint Helen Park as President, and Wayne Mitchell as Treasurer.

Second: Adam Porath

Action: Passed unanimously.

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

    A. Sage Surgical and Neuromodulation, LLC – Reno, NV

Mary Grear (Managing Pharmacist), Michele McCarthy (Pharmacy Consultant), and Ali Nairizi (President of Nevada Pain and Urgent Care and Reno Tahoe Pain Associates and Part Owner of Sage Surgical and Neuromodulation) appeared and were sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave a brief background of the application and questioned where the building is located, if it is separate from Dr. Sasse's practice, and what the purpose is for opening a new location. In addition, Mr. Wuest questioned on what services will be provided, what a typical modulator surgery is, and what drugs they will have on hand.

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

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Ambulatory Surgery Center License for Sage Surgical and Neuromodulation, LLC.

Second: Adam Porath

Action: Passed unanimously.

Gener Tejero and Wayne Mitchell were excused from the meeting at 2:00PM.

27. Executive Secretary Report:

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

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David Wuest presented the Executive Secretary Report to the Board's Satisfaction.

Yenh Long, Deputy Secretary for the Nevada Board of Pharmacy, explained the background of the CE audit that caused a high number of citations of fines that Mr. Wuest mentioned in the Executive Secretary Report.

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

    A. Martha Oppong

Martha Oppong appeared and was sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary of Nevada Board of Pharmacy, gave a brief overview of Ms. Oppong's request to retake the MPJE Exam.

President Park questioned applicant on what occurred in the past exams and what she has been doing to prepare for the exam.

Ms. Oppong answered Board's questions.

President Park reminded Ms. Oppong that the laws in Idaho will be different to the ones in Nevada and to remember that as she continues her studying.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to authorize Martha Oppong to retake the MPJE up to two times within the next six (6) months.

Second: Krystal Freitas

Action: Passed unanimously.

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

    A. Hernan Kim Mok

Hernan Kim Mok appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park disclosed that she knows Mr. Kim Mok from her time at Roseman University but she can participate in this matter fairly and without bias.

DRAFT

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, gave a brief overview of the application and questioned Mr. Kim Mok on his previous discipline with the Board and what he has been doing in the meantime.

President Park questioned Mr. Kim Mok about his discipline and how he plans to deal with the stress in the industry moving forward.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to reinstate Hernan Kim Mok's Pharmacist Registration No. 19930 with the following conditions: 1) he participates in a PRN-PRN or equivalent evaluation program for a period of five years and to send quarterly reports to the Nevada Board of Pharmacy; 2) may not work a maximum of 40 hours per week; and 3) if he would like to become a Pharmacist in Charge (PIC) that he must petition the Board.

Second: Adam Porath

Action: Passed unanimously.

Gener Tejero returned to the meeting at 2:39PM.

19. Approval of Pharmaceutical Technician in Training Application – Appearance **(FOR POSSIBLE ACTION)**

    A. Danisha Faleah Harvey

Danisha Faleah Harvey appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel, gave a brief overview of the application and questioned Ms. Harvey on why she wants to be a pharmacy technician, her discipline disclosure, and her current employment.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Pharmaceutical Technician in Training Application for Danisha Harvey.

Second: Adam Porath

Action: Passed unanimously.

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

A. Robert Toledo

Robert Toledo was sworn in by President Park prior to answering questions and offering testimony.

Bridget Kelly, Esq. appeared as counsel on behalf of Dr. Toledo.

Gener Tejero disclosed that he is familiar with Dr. Toledo but can participate in this matter fairly and without bias.

David Wuest, Executive Secretary of Nevada Board of Pharmacy, gave a brief overview of the application, what discipline occurred in the past with Dr. Toledo, and what he will be using the dispensing license for.

The Board questioned Dr. Toledo on his practice and if he is familiar with the counseling and labeling requirements for take-home medications.

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

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Dispensing Practitioner Registration for Dr. Robert Toledo.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. Cornelious Pryor III

Cornelious Pryor III appeared and was sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary of Nevada Board of Pharmacy, gave a brief overview of the application, clarified with Dr. Pryor III that he does not want to include Schedule I drugs on his application, and explained the disclosures on his application.

Dr. Pryor confirmed that he would like Schedule I's removed from his application.

Board discussion ensued.

Board Action:

Motion: Gener Tejero moved to approve the Controlled Substance Registration application for Dr. Cornelious Pryor III with Schedule's II-V with the condition to do a 1-hour zoom PMP meeting with Darla Zarley.

Second: Adam Porath

Action: Passed unanimously.

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

    B. Signio Specialty Pharmacy – Cliffside Park, NJ

Yoon Young "Kay" Kim (Pharmacist in Charge) and Carlos Cruz (Vice President of Government and Regulatory Affairs) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge, Inspector for the Nevada Board of Pharmacy, gave a brief overview of the application and questioned the applicants about the ownership change, if any changes occurred at the pharmacy, if compounding will take place at the pharmacy, their previous inspection results, and their past discipline.

Ms. Kim and Mr. Cruz answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the change of ownership for the Out-of-State Pharmacy License for Signio Specialty Pharmacy.

Second: Adam Porath

Action: Passed unanimously.

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

    B. Elite Rx – Las Vegas, NV

Jeffrey Lang, Elite Rx Representative, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge, Inspector for Nevada Board of Pharmacy, gave a brief overview of the application and questioned the applicant about his work experience and if they plan to do sterile compounding.

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

Mr. Lang wanted to clarify that he originally sent the request as a change an ownership and amended the application for a new pharmacy license.

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, requested to table application as they get clarification on his application.

President Park tabled application and will return back to agenda item.

9. Application for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6942) – Appearance (**FOR POSSIBLE ACTION)**

    A. Super Care Health – Sparks, NV

Mark Bradshaw, Representative, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, gave a brief overview of the application and questioned the applicant on their prior disciplinary actions.

The Board questioned who the administrator will be and her work experience.

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

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Nevada Medical, Devices, Equipment and Gases License for Super Care Health.

Second: Krystal Freitas

Action: Passed unanimously.

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

DRAFT

C. Elite Rx – Las Vegas, NV

President Park returned to Elite Rx.

Jeffrey Lang, Elite Rx representative, is still sworn in from previously.

David Wuest, Executive Secretary of Nevada Board of Pharmacy, shared the background on what occurred with this application and questioned the respondent on if he is petitioning the Board for a new pharmacy application.

Mr. Lang confirmed.

Board Action:

Motion: President Park moved to approve the new Nevada Pharmacy License for Elite Rx with the conditions to send in the new pharmacy application to exclude non-sterile compounding and must appear before the Board if they decide to do it and a favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. Premier Pharmacy – San Antonio, TX

No representative was present on behalf of Premier Pharmacy.

15. Distributor for Nevada Single Manufacturer (NAC 639.593(6)(e)) – Appearance **(FOR POSSIBLLE ACTION)**

A. DESS-USA – Reno, NV

No representative was present on behalf of Premier Pharmacy.

25. General Counsel Report.

Gregory Zunino presented the General Counsel's Report to the Board's satisfaction

28. Public Comment

President Park opened the floor for public comment.

DRAFT

There was no public comment.

27. Date and Location of Next Scheduled Board Meeting:

September 4-5, 2024 – Las Vegas, NV

29. Adjournment

DRAFT

4

4A

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: American Wound Care Pros, LLC

MDEG Physical Address: 3113 S. University Dr., Ste. 303

City: Fort Worth State: TX Zip: 76109

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 682-250-3149 Website: _____

Email: kdouglas@thewoundpros.com

Name of MDEG Administrator (NAC 639.694): Kristie Douglas

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9:00a-5:00p	■ Tue: 9:00a-5:00p	■ Wed: 9:00a-5:00p	■ Thurs: 9:00a-5:00p	☐ Fri:
☐ Sat:	☐ Sun:	☐ Holidays:		

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

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

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): _____

Corporation/Organization Name: American Wound Care Pros, LLC

Mailing Address: 3113 S. University Dr., Ste. 303

City: Fort Worth State: TX Zip: 76109

Telephone: 682-250-3149 Email: Kdouglas@horizonwoundcare.com

Contact Person Name: Kristie Douglas

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Garrett Adams

Print Name of Authorized Person Submitting Application

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

April 28, 2024

Date

Board Use Only	Date Received: 5/13/24	Amount: $500-cc

NEVADA STATE BOARD OF PHARMACY

Section 9: Provide all the applicable documents with your application based on your business type. Required documents are indicated by an "[checkmark]" on the right:

- **List of <u>all</u> Officers and Directors**

  Garrett Adams
  Sole Member and Managing Member

- **Certificate of Corporate Status or Certificate of Good Standing**

  See **EXHIBIT "A"**

- **Medical Products provider located outside of this State must submit evidence that the medical products provider is licensed permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable)**

  See **EXHIBIT "B"**

- **Copy of proof of insurance (NAC 639.6946)**

  See **EXHIBIT "C"**

- **Personal History Record Application**

  See **EXHIBIT "D"**

- **MDEG Administrator Application (NAC 639.694)**

  See **EXHIBIT "E"**

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for American Wound Care Pros, LLC (file number 805012970), a Domestic Limited Liability Company (LLC), was filed in this office on April 12, 2023.

It is further certified that the entity status in Texas is in existence.

Delayed Effective date: April 14, 2023

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on May 02, 2024.

Jane Nelson
Secretary of State

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

AMERICAN WOUND CARE PROS LLC
3113 S UNIVERSITY DR STE 303
FORT WORTH TX 76109

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

AMERICAN WOUND CARE PROS LLC

3113 S UNIVERSITY DR STE 303
FORT WORTH, TX 76109

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

DEVICE DISTRIBUTOR

License # 1003255
Expires: July 18, 2025

NON-TRANSFERABLE

M.D.
Commissioner

513909

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 02/05/2024

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

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

PRODUCER State Farm CRAIG BAGLEY 1916 Martin Dr Weatherford, TX 76086	CONTACT NAME: PHONE (A/C, No, Ext): 817-594-0241 FAX (A/C, No): 817-599-6433 E-MAIL ADDRESS:
INSURED AMERICAN WOUND CARE PROS 3113 S. UNIVERSITY DR STE 303 FT WORTH TX 76109	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : State Farm Lloyds — 43419 INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

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

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

INSR LTR	TYPE OF INSURANCE	ADD INSD	SUB WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 3,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 500,000
							MED EXP (Any one person)	$ 5,000
				93-G7-R959-4	07/12/2023	07/12/2024	PERSONAL & ADV INJURY	$ 3,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 6,000,000
	POLICY PRO-JECT X LOC						PRODUCTS - COMP/OP AGG	$ 6,000,000
	OTHER							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE / OTH-ER	$
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A						E.L. EACH ACCIDENT	$
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

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

CERTIFICATE HOLDER

National Provider Enrollment (NPE) West
Palmetto GBA, AG-495
P.O. Box 100142
Columbia, SC 29202-3142

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

CRAIG BAGLEY

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NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: American Wound Care Pros, LLC

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

Physical Address: 3113 S. University Dr., Ste. 303

City: Fort Worth State: TX Zip: 76109

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 682-250-3149 Website:

Licensing Company Email: kdouglas@thewoundpros.com

Section 2: Personal Information

First: Garrett Middle: Last: Adams

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

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

Mailing Address: 3113 S. University Dr., Ste. 303

City: Fort Worth State: TX Zip: 76109

Telephone: [redacted] Email: [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of California, Irvine		08/96-05/00	
Address	**City**	**State**	**Zip**
401 E. Peltason Drive	Irvine	CA	92617
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Huntington Beach High School		08/90-05/94	
Address	**City**	**State**	**Zip**
1905 Main Street	Huntington Beach	CA	92648
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/20-Present	[redacted] Beach Blvd., #233	Huntington Beach	CA	92648
01/11-01/20	[redacted] Owego Ave., #4	Huntington Beach	CA	92648
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
ViaDerma Pharma			01/16-Present
Business Address	**City**	**State**	**Zip**
1050 E. Flamingo Road, Suite 107-1360	Las Vegas	NV	89119
Phone	**Title**		
800-585-8685	President (OWNER)		
Description of Duties			
making major corporate decisions, driving the workforce and resources of a company toward strategic goals, and acting as the main point of communication			

Business Name			From - To (MM/YY – MM/YY)
Royce Consulting			01/23-Present
Business Address	**City**	**State**	**Zip**
5049 Edwards Ranch Rd, 4th Floor	Fort Worth	TX	76109
Phone	**Title**		
714-585-5456	President (OWNER)		
Description of Duties			
making major corporate decisions, driving the workforce and resources of a company toward strategic goals, and acting as the main point of communication			

Business Name			From - To (MM/YY – MM/YY)
Builders Network			01/15-12/16
Business Address	**City**	**State**	**Zip**
1050 E Flamingo Rd, Suite 107-1360	Las Vegas,	NV	89119
Phone	**Title**		
800-896-4226	COO (PARTNER)		
Description of Duties			
corporate operations, sales and marketing			

Business Name			From - To (MM/YY – MM/YY)
ENVER Energy			01/11-12/15
Business Address	**City**	**State**	**Zip**
17542 17th St #175	Tustin	CA	92780
Phone	**Title**		
714-640-2340	Director of Sales (SHAREHOLDER)		
Description of Duties			
sales team trainer and manager			

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

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

Garrett, Adams

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

April 28, 2024

Date

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

State of _____, ss. County of _____

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

Julien Rickard – See Attached

Original Signature

Date

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

Notary Public Signature

(Seal)

ACKNOWLEDGMENT

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

State of California
County of Orange)

On April 28, 2024 before me, Julien Rickard , notary public
(insert name and title of the officer)

personally appeared Garrett Adams,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

JULIEN RICKARD
COMM. #2336045
Notary Public - California
Los Angeles County
My Comm. Expires Oct. 20, 2024

Signature _____ **(Seal)**

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

State of California
County of Orange

Subscribed and sworn to (or affirmed) before me on this 28 day of April, 2024, by Garrett Adams, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

JULIEN RICKARD
COMM. #2336045
Notary Public - California
Los Angeles County
My Comm. Expires Oct. 20, 2024

(Seal)

Signature

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: American Wound Care Pros, LLC MDEG License # (if applicable): _____

Physical Address: 3113 S. University Dr., Ste. 303

City: Fort Worth State: TX Zip: 76109

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 682-250-3149 Website: _____

Licensing Company Email: kdouglas@thewoundpros.com

Section 2: Personal Information

First: Kristie Middle: _____ Last: Douglas

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

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

Mailing Address: [redacted] Scenic Trail

City: Willow Park State: TX Zip: 76087

Telephone: [redacted] Email: kdouglas@thewoundpros.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
Vernon High School			08/78-05/82	
Address		**City**	**State**	**Zip**
2102 Yucca Lane		Vernon	TX	76384
Diploma/Degree obtained, if any				
High School Diploma				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/15-Present	[redacted] Scenic Trail	Willow Park	TX	76087
05/13-05/15	[redacted] Raven Band	Hudson Oaks	TX	76087
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Horizon Wound Care			06/23-Current	
Business Address		**City**	**State**	**Zip**
6777 Camp Bowie Blvd		Ft Worth	Tx	76116
Phone	**Title**		**Number of Employed Hours**	
817-353-2062	Operation and Compliance Mgr		1,920	

Description of Duties

Obtain accreditation with HQAA(Healthcare Quality Association on Accreditation) for DME entities to ensure our survey is granted accreditation. Ensure the DME's stay in compliance with Medicare and HQAA guidelines. Perform internal audits on Patient Medical Records, Patient Files, Medical Claims, Personnel Files, Quality Improvement, write Policies and

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Kristie Douglas, **certify that as the MDEG Administrator for**

American Wound Care Pros, LLC,

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

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

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

Kristie Douglas
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/2/2024
Date

Board Use Only	Date Received: 5/13/24

4B

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

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

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

Section 1: General Information

Facility Name: Geron Corporation

Physical Address: 919 E. Hillsdale Blvd, Suite 250

City: Foster City State: CA Zip: 94044

Mailing Address (if different from physical address): SAME

City: _____ State: _____ Zip: _____

Telephone: 650-473-7700 Website: www.geron.com

Name of Designated Representative (DR): Patrick Murphy

Licensing Company Email: statelicensing@geron.com DR Email: pmurphy@geron.com

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

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

Name: Cardinal Health 105, LLC, Specialty Pharmaceutical Services

Address: 15 Ingram Boulevard City: La Vergne State: TN Zip: 37086

Name: Patheon Italia Spa, a subsidiary of Patheon UK, Ltd.

Address: Via Morolense, 5, City: Ferentino FR State: Italy Zip: 03013

Name: Catalent Indiana, LLC

Address: 1300 S. Patterson Drive City: Bloomington State: IN Zip: 47403

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware, 11/28/1990

Parent Company (if any): N/A

Corporation Name: Geron Corporation

Mailing Address: 919 E. Hillsdale Blvd, Suite 250

City: Foster City State: CA Zip: 94044

Telephone: 650-473-7700 Email: statelicensing@geron.com

Contact Person Name: Pam Smith

Date of SEC Registration: 02-28-2008	SEC Registration Number: 0-20859	Stock Exchange Symbol: GERN

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

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

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7_1_2019_Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

Geron Corporation

Facility Name

Andrew Grethlein

Print Name of Authorized Person Submitting Application

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

08MAY24

Date

Board Use Only	Date Received: 6/12/24	Amount: $1000-CK 102664

U.S. FOOD & DRUG ADMINISTRATION

NDA 217779

NDA APPROVAL

Geron Corporation
Attention: Sherrie Pettiford, MS, RAC
Senior Director, Regulatory Affairs
919 E. Hillsdale Boulevard, Suite 250
Foster City, CA 94404

Dear Sherrie Pettiford:

Please refer to your new drug application (NDA) dated June 16, 2023, received June 16, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RYTELO (imetelstat) for injection.

This NDA provides for the use of RYTELO (imetelstat) for injection for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The SPL will be accessible via publicly available labeling repositories.

---

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Attachment to Geron Corporation's Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

Business Description

Geron Corporation is a virtual manufacturer selling prescription drugs to other wholesalers, hospitals, pharmacies and practitioners. As a virtual manufacturer, Geron Corporation does not manufacture, maintain or warehouse any non-controlled or controlled substances at its Foster City, CA facility. As a result, Geron Corporation does not have a DEA registration. The Foster City, CA facility is Geron Corporation's corporate headquarters.

Geron Corporation's hours of operations are Monday through Friday from 8:00 a.m. to 5:00 p.m. PT.

Corporate Officers

Name	Title	Address / Phone
John Archibald Scarlett	President, Chief Executive Officer, and Chairman of the Board	[redacted]Far View Drive Austin, TX 78730 [redacted] Travis County
Michelle Joanne Robertson	Executive Vice-President, Finance, CFO and Treasurer	[redacted]Warren St. Unit 102, Charlestown, MA 02129 [redacted] Suffolk County
Andrew Jacob Grethlein	Executive Vice-President and COO	[redacted]Johnstone Lane Barnard, VT 05031 [redacted] San Franciso County
Faye Miriam Feller	Executive Vice-President and Chief Medical Officer	[redacted]Rector Place, 8Y New York, NY 10280 [redacted] New York County
Anil Kapur	Executive Vice-President, Corporate Strategy and Chief Commercial Officer	[redacted]Wellington Drive Basking Ridge, NJ 07920 [redacted] Somorset County

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "GERON CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF MARCH, A.D. 2024.

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "GERON CORPORATION" WAS INCORPORATED ON THE TWENTY-EIGHTH DAY OF NOVEMBER, A.D. 1990.

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





2247797 8300

SR# 20240932278

Authentication: 202978128

Date: 03-08-24

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

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 8259

ISSUE DATE SEPTEMBER 11, 2023

GERON CORPORATION
919 E HILLSDALE BLVD SUITE 250
FOSTER CITY CA 94044

The above is licensed with the State Board of Pharmacy as a Corporation.

CORPORATION
PATRICK MICHAEL MURPHY EXEMPTEE IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL SEPTEMBER 01, 2024

RECEIPT NUMBER 00740377

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

1/23
1/23

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

GERON CORPORATION (1522939)



Request Certificate

Initial Filing Date	03/31/1992
Status	Active
Standing - SOS	Good
Standing - FTB	Good
Standing - Agent	Good
Standing - VCFCF	Good
Formed In	DELAWARE
Entity Type	Stock Corporation - Out of State - Stock
Principal Address	919 EAST HILLSDALE BLVD, SUITE 250 FOSTER CITY, CA 94404
Mailing Address	919 EAST HILLSDALE BLVD, SUITE 250 FOSTER CITY,CA94404
Statement of Info Due Date	03/31/2025
Agent	1505 Corporation C T CORPORATION SYSTEM
CA Registered Corporate (1505) Agent Authorized Employee(s)	AMANDA GARCIA 330 N BRAND BLVD, GLENDALE, CA GABRIELA SANCHEZ 330 N BRAND BLVD, GLENDALE, CA

Attachment to Geron Corporation's Private Label Distributor Application (Alabama Board of Pharmacy)

Omeros Corporation Ownership

Geron Corporation is a publicly traded company (NASDAQ:GERN). As a publicly traded corporation, ownership changes frequently and to a certain extent cannot be determined, due to shareholders holding their shares in a broker's name.

The following are the two largest historical shareholders, which are the only two who have made filings with the SEC indicating that they hold (or held) at least 5% of the company's outstanding shares (as of the date the filing was made). Below is an estimated breakdown of Geron Corporation's shareholders as of February 27, 2024, based on information from Geron Corporation.

Omeros Corporation Ownership cont.

Top 5 Holders of Institutional Holdings

Stockholder Name	**Share %**
Ra Capital Management, L.P. is 200 BERKELEY STREET, 18TH FLOOR, BOSTON, Massachusetts, 02116	11.74
Blackrock Inc is 50 HUDSON YARDS, NEW YORK, New York, 10001	10.72
Deep Track Capital, Lp is 200 GREENWICH AVENUE, GREENWICH, Connecticut, 06830	7.52
Vanguard Group Inc is PO BOX 2600, VALLEY FORGE, Pennsylvania, 19482-2600	7.26
State Street Corp is 1 CONGRESS STREET, BOSTON, Massachusetts, 02114	6.52
Institutional Shares	56.24

First Name	Last Name	Job Title
Nova	Ahrens	Associate Director, Financial Planning & Analysis - Commercial and Medical Affairs
John	Albert	Director, Information Technology Infrastructure
Jennifer	Allen	Director, Talent Acquisition
Frank	Andel	Senior Director, Analytical Sciences
Gregory	Angelovic	National Account Director, GPO & Physician Networks
Peter	Avalos	Vice President, US Trade and Channel Relations
Felix	Bakthasekaran	Senior Manager, Clinical Program Management
Ronan	Balicanta	Associate Director, Regulatory Affairs - Operations Lead
Michael	Balter	Associate Director, Information Technology Infrastructure
Bharat	Baral	Senior Manager, CMC
Neeru	Batra	Director, Clinical Program Management
AnnaMarie	Bauer	Director, Revenue and Gross to Net Accounting
Melissa	Behrs	Executive Vice President, Business Operations & Chief Alliance Officer
Abby	Berghella	Senior Trademark and Patent Paralegal II
Tymara	Berry	Vice President, Clinical Development
Jay	Blatnik	Senior Manager, Information Technology Business Systems
Yvonne	Bleam	Senior Director, Training and Development
Niraja	Bohidar	Statistical Programming Manager
Jeffrey	Braziunas	Senior Director, Medical Affairs Strategy and Field Medical Excellence
Kelli	Brillhart	Corporate Paralegal
Nora	Bruno	Senior Director, Clinical Quality Assurance
Yun	Cai	Commercial Application and Data Management Senior Manager
Paula	Cassidy	Executive Director, Marketing
Marissa	Cerniglia	Senior Manager, People Operations
Leslie	Cherette	Director, CMC Program Management
Miranda	Chrisp	Director, Clinical Program Management
Dana	Clark	Community Medical Science Liaison - Southeast
David	Clark	Vice President, Finance & Controller
Christopher	Cornell	Senior Field Medical Liaison
Catherine	Curry	Senior Manager, Quality Assurance
Stephanie	Dellari	Director, Human Resources
Joseph	Denton	Senior Director, Quality
Souria	Dougherty	Executive Director, Clinical Science
Allyson	Dusza	Associate Director, Product Training
Eric	Elbel	Associate Director, Logistics
James	Evans	National Account Director, Payer & Channel Access
Rana	Farha	Senior Director, Statistical Programming
Angela	Federici	Director, Market Research
Aron	Feingold	Vice President, Investor Relations and Corporate Communications
Faye	Feller	Executive Vice President & Chief Medical Officer
Susan	Finan	Senior Director, Human Resources
Casey	Flores	Director, Field Reimbursement & Access - West
Gillian	Fong	Senior Director, Finance
Mary	Foster	Executive Assistant
Herminia	Franks	Senior Payroll Administrator
Laurence	Gamelin	Vice President, Pharmacovigilance and Drug Safety
Stefani	Gao	Buyer, Strategic Sourcing
Damarys	Garcia	Senior Manager, Strategic Sourcing
Oliver	Gessner	Executive Director, Business Insights and Analytics
Karla	Goins	Director, Field Reimbursement & Access - Central
Ryan	Goldstein	Senior Director, Trade, Distribution, and HUB
Andrew	Grethlein	Executive Vice President & Chief Operating Officer

Denise	Grippo	Vice President, Quality
Jason	Grossman	Executive Director, Commercial Operations
Stewart	Hackney	Senior Director, GPO, Field Reimbursement, and National Accounts
Teri	Hammer-Rosenski	Director, Human Resources Business Partner
Katherine	Harmon	Senior Director, Finance & Assistant Controller
Sarfraz	Haroon	Associate Director, Clinical Data Management
Andrea	Hernandez	Accounts Payable Specialist
Hoang	Ho	Associate Director, Clinical Science
Michelle	Hoff	Associate Director, Clinical Operations
Ryan	Holmbeck	Associate Director, Supply Chain Planning
Anthony	Holt	Regional Business Director - West
Fei	Huang	Executive Director, Translational Research and Clinical Pharmacokinetics
Travis	Humphreys	Director, Clinical Quality Assurance
Jessica	Hurado	Senior Manager, Biomarker Operations
Jason	Hutson	Vice President, Sales
Annat	Ikin	Director, Medical Writing
Nisha	Javeri	Associate Director, Professional Marketing
Aswin	Jayaraman	Director, Information Technology Business Systems - Commercial
Christopher	Johnson	Senior Director, Legal Counsel
Melanie	Johnson	Field Force Coordinator - West
Brandie	Jonas	Senior Director, Clinical Program Management
Brent	Jones	Director, Information Technology Business Systems
Anita	Kane	Field Force Coordinator - East
Anil	Kapur	Executive Vice President, Corporate Strategy & Chief Commercial Officer
Kristen	Kelleher	Associate Director, Investor Relations and Corporate Communications
Gayle	Kempinski	Community Medical Science Liaison - North Central
Sami	Khan	Commercial Excellence Manager
Edward	Koval	Executive Vice President & Chief Business Officer
Anthony	Kuczynski	Director, Information Technology Compliance
Rachel	Ladd	Associate Director, Statistical Programming
Chen-Yi	Lee	Senior Accountant
Ashley	Lennox	Associate Director, Clinical Pharmacology
Kathleen	Lindner	Director, Field Reimbursement & Access - Northeast
Nicholas	Lyon	Senior Director, CMC Regulatory Affairs
Shannon	Maryman	Director, Field Reimbursement & Access - Southeast
Carissa	Mazurick	Associate Director, Statistical Programming
Fiona	McAuliffe	Talent Acquisition Associate
Sharon	McBain	Senior Vice President, Global Regulatory Affairs
Thomas	McLaughlin	Senior Director, Global Pricing & Contracting
Nicole	McMahon	Director, Patient Marketing
Lisa-Beth	Meletta	Vice President, Commercial Legal, Associate General Counsel, and Chief Compliance Officer
Julia	Mensing	Executive Assistant
Denise	Meyer	Vice President, Medical Affairs
Tamara	Millner	Senior Director, Commercial Counsel
Shirin	Mirshamsi	Senior Director, Regulatory Affairs - EU Lead
Natasha	Moningka	Senior Field Medical Liaison
Dana	Montgomery	Senior Director, Regulatory Affairs Labeling
Leslie	Mooi	Vice President, Intellectual Property
Natasha	Moore	Associate Director, Clinical Operations
Goziem	Mordi	Senior Manager, Global Regulatory Affairs
Jamie	Mortellite	Community Medical Science Liaison - Northeast
Eric	Mueller	Senior Director, Process Development and Manufacturing
Patrick	Murphy	Vice President, Manufacturing

Patricia	Nash	Executive Director, Drug Safety Operations
Shyamala	Navada	Executive Medical Director, Clinical Science
Lynn	Neilson	Director, Scientific Communications and Publications
My-Ngoc	Nguyen	Senior Accountant
Kimberlee	Nickell	Contracts Manager
Shannon	Odam	Senior Vice President & Chief People Officer
Caroline	Pak	Senior Director, Medical Information and Scientific Communications
Ankita	Patel	SEC and Equity Reporting Senior Manager
Nirali	Patel	Senior Field Medical Liaison
Lixian	Peng	Director, Biostatistics
Sherrie	Pettiford	Senior Director, Regulatory Affairs
BichMai	Pham	Senior Office Manager
Jeremy	Raelin	Director, Commercial Data and Technology Operations
Denise	Redding	Director, Pharmacovigilance and Drug Safety
Laura	Reederson	Director, Legal Counsel
Jennifer	Riggs	Associate Director, Clinical Science
Alejandro	Rivas	Endpoint Engineer, Information Technology Infrastructure
Michelle	Robertson	Executive Vice President & Chief Financial Officer
Vivian	Rodolf	Medical Director, Clinical Science
William	Rodriguez	Director, Drug Product Manufacturing
Jeffrey	Ryel	Senior Director, Clinical Operations
Guillermo	Salas	Regional Business Director - Southeast
Scott	Samuels	Executive Vice President & Chief Legal Officer
Ilesh	Sanathra	Senior Director, Regulatory Affairs - Global Projects Lead
Alexander	Sardinas	Regional Business Director - Northeast
John	Scarlett	Chief Executive Officer
Megan	Schaeffer	Vice President, Clinical Operations
Jolinda	Schulte	Regional Business Director - Central
Nishan	Sengupta	Vice President, Market Access and Pricing
Sheetal	Shah	Senior Director, Clinical Science
Edmund	Shangold	Director, Digital Marketing
Jefferson	Shatzen	Quality Assurance Manager
Jyotilaxmi	Shetty	Senior Director, Information Technology
Sara	Shinnick	Senior Field Medical Liaison
Lorraine	Shui	Vice President, Marketing
Damanjit	Singh	Associate Director, Quality Systems
Pamela	Smith	Vice President, Legal Affairs and Associate General Counsel
Sridevi	Sridhar	Associate Director, Clinical Data Management
Michael	Steidle	Executive Director, National Field Medical Teams
Libo	Sun	Senior Director, Biostatistics
Rui	Sun	Associate Director, Analytical Sciences
Dylan	Supina	Senior Director, Real World Evidence Analytics and Strategy
Jillian	Swogier	Director, Commercial Contracting and Trade Counsel
Mary	Szekeres	Senior Director, Channel Marketing
Vallinayagam	Thirunavukkarasu	Director, Forecasting
Benjamin	Thorp	Senior Director, Data Management
Timothy	Tickner	Senior Director, Supply Chain Management
Gregory	Titone	Regional Business Director - Gulf Coast
Katelynne	Turner	Associate Director, Clinical Operations
Despina	Valsamis	Medical Affairs Senior Manager
Ryan	Vincenti	Associate Director, Commercial Excellence
Jeanette	Wall	Associate Director, Clinical Quality Assurance
Ying	Wan	Vice President, Biometrics and Data Management

Stacie	Wanic	Manager, Commercial Administration and Launch Readiness
Samantha	Ward	Director, Regulatory Compliance
Timothy	Williams	Associate Director, Information Technology Business Systems - G&A
Kellie	Winemiller	Director, Field Reimbursement & Access - Gulf Coast
Leah	Wood	Manager, Quality Systems
Qi	Xia	Associate Director, Biostatistics

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2023

or

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

For the transition period from _____ to _____.

Commission File Number: 000-20859

GERON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**75-2287752**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
919 East Hillsdale Blvd., Suite 250, Foster City, CA	**94404**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 473-7700

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

Title of each class:	**Trading symbol(s):**	**Name of each exchange on which registered:**
Common Stock, $0.001 par value	GERN	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $1,394,546,000 based upon the closing price of the registrant's common stock on June 30, 2023 on the Nasdaq Global Select Market. The calculation of the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant excludes shares of common stock held by each officer, director and stockholder that the registrant concluded were affiliates on that date. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 23, 2024, there were 546,059,309 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Document	**Form 10-K Parts**

TABLE OF CONTENTS

		Page
	PART I	
Item 1.	Business	5
Item 1A.	Risk Factors	31
Item 1B.	Unresolved Staff Comments	69
Item 1C.	Cybersecurity	69
Item 2.	Properties	70
Item 3.	Legal Proceedings	70
Item 4.	Mine Safety Disclosures	70
	PART II	
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	71
Item 6.	[Reserved]	71
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	71
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	82
Item 8.	Financial Statements and Supplementary Data	82
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	116
Item 9A.	Controls and Procedures	116
Item 9B.	Other Information	117
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	117
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	117
Item 11.	Executive Compensation	118
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	118
Item 13.	Certain Relationships and Related Transactions, and Director Independence	118
Item 14.	Principal Accountant Fees and Services	118
	PART IV	
Item 15.	Exhibits and Financial Statement Schedules	118
Item 16.	Form 10-K Summary	122
	SIGNATURES	123

In this report, unless otherwise indicated or the context otherwise requires, "Geron," "the registrant," "we," "us," and "our" refer to Geron Corporation, a Delaware corporation, and its wholly owned subsidiaries, Geron UK Limited, a United Kingdom company, and Geron Netherlands, B.V., a Dutch company.

PART I

ITEM 1. BUSINESS

Company Overview

We are a late-stage biopharmaceutical company pursuing therapies with the potential to extend and enrich the lives of patients living with hematologic malignancies. Our investigational first-in-class telomerase inhibitor, imetelstat, harnesses Nobel Prize winning science in a treatment that may alter the underlying course of these diseases.

Our lead indication for imetelstat is in lower-risk MDS. In August 2023, our NDA for the treatment of transfusion-dependent anemia in adult patients with low to-intermediate-1 risk MDS who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents, or ESAs, was accepted by the United States, or U.S., FDA, for review and assigned a Prescription Drug User Fee Act, or PDUFA, action date of June 16, 2024. In addition, the FDA has scheduled an advisory committee meeting as part of the NDA review on March 14, 2024. If imetelstat is approved for commercialization by the FDA, we anticipate commercial launch of imetelstat in lower-risk MDS in the U.S. could occur at the time of approval. In September 2023, we submitted an MAA in Europe that was validated for review by the EMA for imetelstat for the same proposed indication as in the U.S. We expect a review of the MAA could be completed in early 2025, and subject to approval by the European Commission, we believe EU commercial launch of imetelstat would occur in 2025.

Our NDA and EMA submissions are based on positive data from the IMerge Phase 3 clinical trial. The trial met its primary endpoint of ≥ 8-week transfusion independence rate and a key secondary endpoint of 24-week transfusion independence rate, demonstrating highly statistically significant (i.e., $p<0.001$ for both) and clinically meaningful benefits with imetelstat treatment versus placebo. Furthermore, statistically significant and clinically meaningful efficacy results were observed in the trial across key subtypes, including patients who were ringed sideroblast positive, or RS positive, and ringed sideroblast negative, or RS negative; patients with high and very high baseline transfusion burden; and patients classified as Low or Intermediate-1 risk according to the International Prognostic Scoring System, or IPSS. Consistent with prior imetelstat clinical experience, the most common serious adverse events were primarily short-lived, manageable thrombocytopenia and neutropenia.

In addition to lower-risk MDS, we are developing imetelstat for the treatment of several myeloid hematologic malignancies, including a Phase 3 clinical trial, named IMpactMF, in patients with Intermediate-2 or High-Risk myelofibrosis who have relapsed after or are refractory to treatment with a janus associate kinase inhibitor, or JAK inhibitor, or relapsed/refractory MF, with overall survival, or OS, as the primary endpoint, that currently is enrolling patients. In November 2023, the trial reached 50% enrollment. Based on our current planning assumptions for enrollment and event (death) rates in the trial, we expect the interim analysis for OS in IMpactMF may occur in the first half of 2025, and the final analysis may occur in the first half of 2026.

We are also conducting a Phase 1 combination therapy clinical trial, named IMproveMF, in first-line Intermediate-1, Intermediate-2 or High-Risk myelofibrosis, or frontline MF, that currently is enrolling patients and imetelstat is being studied in an investigator-led Phase 2 clinical trial, named IMpress, in Intermediate-2 or High-Risk myelodysplastic syndromes, or higher risk MDS, and acute myeloid leukemia, or AML, in which the first patient was dosed in June 2023.

We believe that the positive data from IMerge Phase 3 and IMerge Phase 2, as well as our prior Phase 2 clinical trial of imetelstat in patients with relapsed/refractory MF, provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells enabling recovery of bone marrow and normal blood cell production, which suggest potential disease-modifying activity. We believe this potential for disease modification could differentiate imetelstat from currently approved treatments in myeloid hematologic malignancies.

Commercial Plans for Imetelstat

If imetelstat is approved in lower-risk MDS for marketing by regulatory authorities, we plan to commercialize imetelstat ourselves in the U.S. Our U.S. launch strategy is designed to prepare imetelstat, the market and the company to ensure broad reimbursement and deliver a seamless customer experience to all stakeholders at launch. Several long-lead time activities have already been completed, such as securing a global trademark for the imetelstat brand name; finalizing third party logistics, our distribution network, and our patient support providers; and onboarding highly experienced commercial and medical affairs leadership teams. We

commercial access/reimbursement preparatory efforts, and hiring our sales force, which we expect to occur in the first and second quarters of 2024. We continue to evaluate our strategy for the potential launch and commercialization of imetelstat in Europe. Based on our internal estimates of pricing and addressable patient populations in 2031 and if regulatory authorities approve imetelstat for marketing in lower-risk MDS and relapsed/refractory MF, we believe the potential combined total addressable market opportunity in the U.S. and Europe for imetelstat is approximately $7.0 billion, of which lower-risk MDS represents approximately $3.5 billion and relapsed/refractory MF represents approximately $3.5 billion.

Background of Telomerase Inhibition in Hematologic Malignancies and Imetelstat

In the human body, normal growth and maintenance of tissues occurs by cell division. However, most cells are only able to divide a limited number of times, and this number of divisions is regulated by telomere length. Telomeres are repetitions of a deoxyribonucleic acid, or DNA, sequence located at the ends of chromosomes. They act as protective caps to maintain stability and integrity of the chromosomes, which contain the cell's genetic material. Normally, every time a cell divides, the telomeres shorten. Eventually, they shrink to a critically short length, and as a result, the cell either dies by apoptosis or stops dividing and senesces.

Telomerase is a naturally occurring enzyme that maintains telomeres and prevents them from shortening during cell division, such as stem cells that must remain immortalized to support normal health. Telomerase consists of at least two essential components: a ribonucleic acid, or RNA, template, which binds to the telomere, and a catalytic subunit with reverse transcriptase activity, which adds a specific DNA sequence to the chromosome ends. The 2009 Nobel Prize for Physiology or Medicine was awarded to Drs. Elizabeth H. Blackburn, Carol W. Greider and Jack Szostak, former Geron collaborators, for the discovery of how chromosomes are protected by both telomeres and telomerase.

Telomerase is upregulated in many tumor cells and malignant stem and progenitor cells, enabling the continued and uncontrolled proliferation of the malignant cells that drive tumor growth and progression. We believe that inhibiting telomerase may be an attractive approach to treating cancer because it may limit the proliferative capacity of malignant stem and progenitor cells, which are believed to be important drivers of tumor growth and progression. We and others have observed in various in vitro, ex vivo and rodent tumor models that inhibiting telomerase: (a) results in telomere shortening and (b) arrests uncontrolled malignant cell proliferation and tumor growth.

Hematologic malignancies, or blood cancers, are classified according to the precursor cell type. A myeloid hematologic malignancy is a cancer that occurs in the myeloid hematopoietic progenitor cells, such as the precursor cells of red blood cells, platelets and certain myeloid white blood cells, such as granulocytes. Myeloid neoplasms include myeloproliferative neoplasms, MDS and AML. Examples of myeloproliferative neoplasms include chronic myeloid leukemia, essential thrombocythemia, or ET, polycythemia vera and MF. These myeloid neoplasms are different from lymphocytic malignancies which typically occur in the lymphoid cell progenitor lineage, such as precursor cells of T lymphocytes and B lymphocytes. Examples of lymphoid malignancies include acute lymphoblastic leukemia, chronic lymphocytic leukemia, lymphomas and multiple myeloma.

Many myeloid hematologic malignancies, such as ET, MF and MDS, have been shown to arise from malignant stem and progenitor cells that express higher telomerase activity and have shorter telomeres when compared to normal healthy cells. In vitro studies have suggested that tumor cells with short telomeres may be especially sensitive to the anti-proliferative effects of inhibiting telomerase.

Imetelstat: The First Telomerase Inhibitor to Advance to Clinical Development

Imetelstat, our proprietary telomerase inhibitor which was discovered and developed at Geron, was designed to inhibit telomerase in malignant cells with continuously upregulated telomerase.

Imetelstat is a lipid conjugated 13-mer oligonucleotide that we designed to be complementary to and bind with high affinity to the RNA template of telomerase, thereby directly inhibiting telomerase activity. Imetelstat does not act as an antisense inhibitor of protein translation. The compound has a proprietary thio-phosphoramidate backbone, which is designed to provide resistance to the effect of cellular nucleases, thus conferring improved stability in plasma and tissues, as well as improved binding affinity to its target. To improve the ability of imetelstat to penetrate cellular membranes, we conjugated the oligonucleotide to a lipid group. Imetelstat's IC50, or half maximal inhibitory concentration, is 3 – 9 nM in cell free assays. Single-dose pharmacokinetics in patients has shown dose-dependent increases in exposure to imetelstat, with a plasma half-life, which is the time it takes for the concentration or amount of

observed at 41 – 45 hours after a 7.5 mg/kg dose in patients. Imetelstat also has been shown in non-clinical studies to exhibit relatively preferential inhibition of the clonal proliferation of malignant progenitor cells compared to normal progenitor cells. For these reasons, imetelstat has been studied as a potential treatment for malignant diseases.

We believe imetelstat is the first telomerase inhibitor to advance to clinical development. The Phase 1 trials that we completed evaluated the safety, tolerability, pharmacokinetics and pharmacodynamic effects of imetelstat. We established doses and dosing schedules that were tolerable and achieved target exposures in patients that were consistent with those required for efficacy in animal models. Following intravenous administration of imetelstat using tolerable dosing regimens, clinically relevant and significant inhibition of telomerase activity was observed in various types of tissue in which telomerase activity is measurable, including normal bone marrow hematopoietic cells, malignant plasma cells, hair follicle cells and peripheral blood mononuclear cells. Dose-limiting toxicities included thrombocytopenia, or reduced platelet count, and neutropenia, or reduced neutrophil count.

Imetelstat's Potential Disease-Modifying Activity

We believe that imetelstat may have the potential to suppress the proliferation of malignant stem and progenitor cells while transiently affecting normal cells. Early clinical data from a Phase 2 trial of imetelstat in patients with ET, or the ET Trial, and a pilot study of imetelstat in patients with MF conducted at Mayo Clinic, or the Pilot Study, suggested that imetelstat inhibits the progenitor cells of the malignant clones believed to be responsible for the underlying diseases in a relatively select manner, indicating potential disease-modifying activity. These data were published in two separate articles in a September 2015 issue of *The New England Journal of Medicine*.

Clinical Development

Pipeline Chart



TD LR-MDS: transfusion-dependent lower-risk myelodysplastic syndromes; R/R MF: relapsed/refractory myelofibrosis; MF: myelofibrosis; R/R AML: relapsed/refractory acute myeloid leukemia; HR MDS: higher risk myelodysplastic syndromes; TI: telomerase inhibitor; PDUFA: Prescription Drug User Fee Act; MAA: marketing authorization application

Lower-Risk Myelodysplastic Syndromes (MDS)

MDS is a group of blood disorders in which the proliferation of malignant progenitor cells produces multiple malignant cell clones in the bone marrow resulting in disordered and ineffective production of the myeloid lineage, which includes red blood cells, white blood cells and platelets. In MDS, bone marrow and peripheral blood cells may have abnormal, or dysplastic, cell morphology. MDS is frequently characterized clinically by severe anemia, or low red blood cell counts, and low hemoglobin. In addition, other peripheral cytopenias, or low numbers of white blood cells and platelets, may cause life-threatening infections and bleeding. Transformation to AML occurs in up to 30% of MDS cases and results in poorer overall survival.

Decision Resources Group, MDS Syndicated Report 2020, 2021, 2022. MDS is primarily a disease of the elderly, with median age at diagnosis around 70 years. The majority of patients, approximately 70%, fall into what are considered to be the lower-risk groups at diagnosis, according to the International Prognostic Scoring System that assigns relative risk of progression to AML and overall survival by taking into account the presence of a number of disease factors, such as cytopenias and cytogenetics.

Chronic anemia is the predominant clinical problem in patients who have lower-risk MDS. Typically, these patients are treated with ESAs, such as erythropoietin, or EPO. Although ESAs provide an improvement in anemia in approximately 50% of patients, the effect is transient with a median duration of response of approximately two years. Once ESAs fail for patients, HMAs and lenalidomide have been used to improve anemia, but with limited success, such as reported ≥ 8-week red blood cell transfusion independence, or RBC-TI, rates of 17% for azacitidine, an HMA, and 27% for lenalidomide in non-del5q lower-risk MDS patients. In August 2023, Reblozyl, or luspatercept, was approved for the treatment of anemia in adult patients with very low-to-intermediate-risk MDS without previous erythropoiesis stimulating agent use, or ESA-naive, who may require regular RBC transfusions. In April 2020, luspatercept was approved for use in a subgroup of ESA-failed lower risk MDS patients – those with ringed sideroblasts. Such patients comprise approximately 15% to 30% of all lower-risk MDS patients. The majority of patients who do not have ringed sideroblasts or who no longer respond to ESAs or other available drug therapies become dependent on red blood cell transfusions due to low hemoglobin. Serial red blood cell transfusions can lead to elevated levels of iron in the blood and other tissues, which the body has no normal way to eliminate. Iron overload is a potentially dangerous condition. Published studies in patients with MDS have shown that iron overload resulting from regular red blood cell transfusions is associated with a poorer overall survival and a higher risk of developing AML.

Phase 3 IMerge Trial in Lower-Risk MDS

IMerge is a two-part Phase 2/3 clinical trial evaluating imetelstat (7.5 mg/kg dose administered as a two-hour intravenous infusion every four weeks) in transfusion dependent lower-risk MDS patients who are relapsed after, refractory to, or ineligible for prior treatment with an ESA. To be eligible for IMerge, patients were required to be transfusion dependent, defined as requiring at least four units of packed red blood cells, or RBCs, over an eight-week period during the 16 weeks prior to entry into the trial.

IMerge Phase 3 is a double-blind, 2:1 randomized, placebo-controlled clinical trial that, based on discussions with U.S. and European regulatory authorities, was designed to support, if successful, the registration of imetelstat in transfusion dependent lower-risk MDS. The trial enrolled patients with transfusion dependent lower-risk MDS who were relapsed, or refractory to, or ineligible for ESA, had not received prior treatment with either a hypomethylating agent, or HMA, or lenalidomide and were non-del(5q). IMerge Phase 3 was conducted at 118 medical centers globally in 17 countries in North America, Europe, Middle East and Asia.

The primary efficacy endpoint of IMerge Phase 3 was the rate of red blood cell transfusion independence, or RBC-TI, lasting at least eight weeks, defined as the proportion of patients without any RBC transfusions during any consecutive eight weeks since entry to the trial, or ≥ 8-week TI. Key secondary endpoints for IMerge Phase 3 included the rate of RBC-TI lasting at least 24 weeks, or 24-week TI, and the rate of hematologic improvement erythroid, or HI-E, which is a rise in hemoglobin of at least 1.5 g/dL above the pretreatment level for at least eight weeks or a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden. Other secondary endpoints included the time to and duration of RBC-TI; the proportion of patients achieving Complete Response, or CR, or Partial Response, or PR, according to the 2006 International Working Group, or IWG, criteria for MDS; the proportion of patients requiring RBC transfusions and the transfusion burden; the proportion of patients requiring the use of myeloid growth factors and the dose; assessments of the change in the patients' quality of life using several validated instruments; as well as an assessment of OS, and time to progression to AML.

In January 2023, we reported positive top-line results from IMerge Phase 3. Additional data were subsequently published at the European Hematology Association Annual Meeting in June 2023, the American Society of Hematology Annual Meeting in December 2023, and in *The Lancet* in December 2023, as summarized below.

A total of 178 patients were enrolled in IMerge Phase 3, with patients randomized on a 2:1 basis to imetelstat (n=118) or placebo (n=60), including patients with a broad range of lower-risk MDS subtypes and with high disease burden. The trial met its primary endpoint of ≥ 8-week TI rate and key secondary endpoint of 24-week TI rate, among others, demonstrating statistically significant and clinically meaningful results with imetelstat versus placebo with no new safety signals and safety results consistent with prior imetelstat clinical trials.

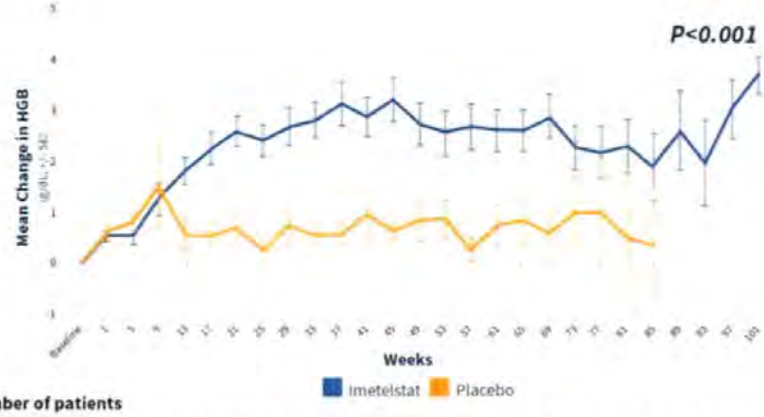
Durability of TI and response rates were significantly higher with imetelstat versus placebo, as summarized below:



8, 16, 24-week data cut off was October 2022; 1-year represents 3 additional months of data (cut off January 2023)
P-value is based on Cochran Mantel Haenszel test stratified for prior RBC transfusion burden (≤6 units or >6 units of RBCs/8 weeks) and baseline IPSS risk score (Low or Intermediate-1)
8-week TI = proportion of patients without any RBC transfusion for at least eight consecutive weeks since entry to the trial; 16-week TI = proportion of patients without any RBC transfusion for at least 16 consecutive weeks since entry to the trial; 24-week TI = proportion of patients without any RBC transfusion for at least 24 consecutive weeks since entry to the trial; 1-year TI = proportion of patients without any RBC transfusion for at least 52 consecutive weeks since entry to the trial

Platzbecker, Santini et al. The Lancet 2023

In addition, highly statistically significant ($p<0.001$) increase in hemoglobin levels over time were observed for imetelstat patients as shown in the graph below. For patients achieving ≥ 8-week TI, median increases in hemoglobin were 3.6 g/dL for imetelstat and 0.8 g/dL for placebo.



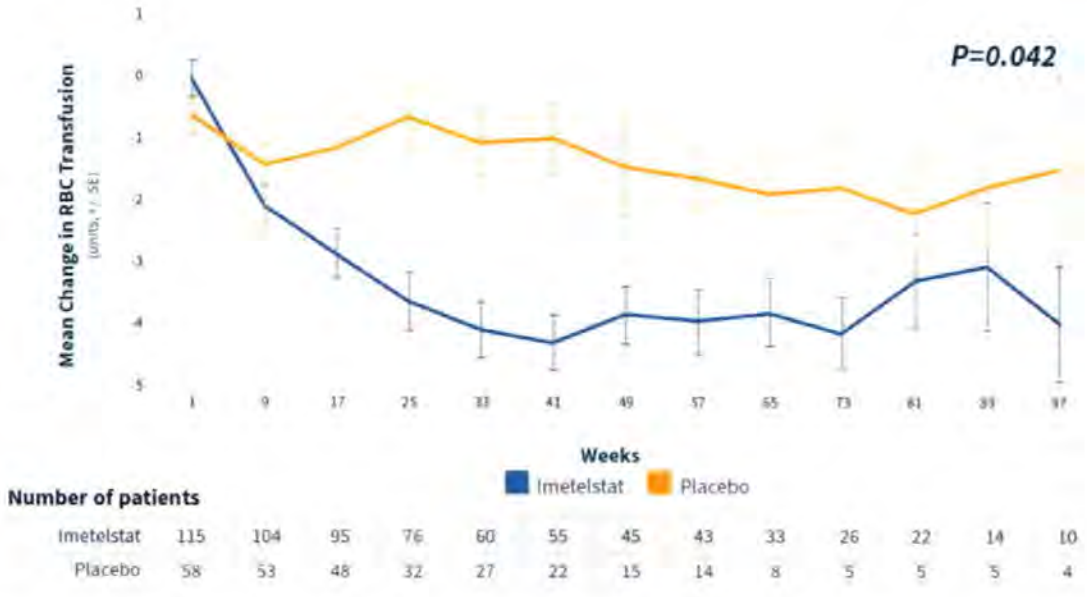
Number of patients

Imetelstat	118	59	53	54	47	42	48	48	43	43	31	37	31	35	32	25	26	24	23	21	19	18	11	11	9	9	5
Placebo	60	37	29	17	16	18	15	8	10	10	11	7	3	9	8	9	7	7	5	5	4	2	4				

The mean changes from the minimum Hgb of the values that were after 14 days of transfusions in the eight weeks prior to the first. Data points that have fewer than four patients are not shown.
P-value is based on a mixed model for repeated measures with Hgb change as the dependent variable, week, stratification factors, dose date, and treatment arm as the independent variables with autoregressive moving average (ARMA(1,1) covariance structure.

Platzbecker, Santini et al. The Lancet 2023

A statistically significant decrease in the number of RBC units transfused was achieved for imetelstat treated patients versus placebo, as shown in the graph below.



P-value is based on a mixed model for repeated measures with change in RBC transfusion as the dependent variable, week, stratification factors, prior transfusion burden, and treatment arm as the independent variables with autoregressive moving average (ARMA(1,1) covariance structure.

Platzbecker, Santini et al. The Lancet 2023

Furthermore, as shown in the table below, statistically significant ≥ 8-week RBC-TI rates were observed with imetelstat versus placebo across lower-risk MDS subtypes ($p<0.05$) and similar ≥ 8-week RBC-TI rates were observed for imetelstat within each subtype category in comparison to the overall population.

	Imetelstat, n (%)	Placebo, n (%)	Difference (95% CI)	P-value*
Overall	47/118 (39.8)	9/60 (15.0)	24.8 (9.9, 36.9)	<0.001
WHO category				
RS+	33/73 (45.2)	7/37 (18.9)	26.3 (5.9, 42.2)	0.016
RS-	14/44 (31.8)	2/23 (8.7)	23.1 (-1.3, 40.6)	0.038
Transfusion burden				
4-6 units	28/62 (45.2)	7/33 (21.2)	23.9 (1.9, 41.4)	0.027
>6 units	19/56 (33.9)	2/27 (7.4)	26.5 (4.7, 41.8)	0.023
IPSS risk category				
Low	32/80 (40.0)	8/39 (20.5)	19.5 (-0.1, 35.2)	0.034
Intermediate-1	15/38 (39.5)	1/21 (4.8)	34.7 (8.8, 52.4)	0.004

* Cochran Mantel Haenszel test stratified for prior RBC transfusion burden (≤6 units or >6 units of RBCs/8 weeks) and baseline IPSS risk score (Low or Intermediate-1)

4C

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: Howmedica Osteonics Corp

Physical Address: 325 Corporate Dr

City: Mahwah State: NJ Zip: 07430

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 201-819-6302 Website: www.stryker.com

Name of Designated Representative (DR): Jimmy Pan

Licensing Company Email: statelicensing1@stryker.com DR Email: jimmy.pan@stryker.com

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

~~N/A~~ See attached

Original Signature (electronic, copies or stamps not accepted)

10 APR 2024
Date

KRISTIN K. MAYES
Attorney General
Firm State Bar No. 14000

JEANNE M. GALVIN
Assistant Attorney General
State Bar No. 015072
SETH T. HARGRAVES
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Tel: (602) 542-7672
Fax: (602) 364-3202

Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of **STRYKER SUSTAINABILITY SOLUTIONS, INC. (Tempe)** **Applicant for Permit (M002150) as a Resident Virtual Manufacturer In the State of Arizona;** **STRYKER SUSTAINABILITY SOLUTIONS, INC. (Phoenix)** **Applicant for Permit (M002160) as a Resident Manufacturer In the State of Arizona;** **HOWMEDICA OSTEONICS, CORP. /STRYKER ORTHOPAEDICS (Tucson)** **Applicant for Permit (W003760) as a Resident Wholesaler In the State of Arizona;** **APPLICANTS**	Case No. 23-0627 **CONSENT AGREEMENT FOR ISSUANCE OF PERMITS AND ORDER FOR CIVIL PENALTY**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.* Stryker Sustainability Solutions ("Stryker Tempe" and "Stryker Phoenix") and Howmedica Osteonics Corp. ("Stryker Orthopaedics") collectively "Applicants", and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1. Applicant has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Applicant understands that it has a right to a public administrative hearing concerning this matter at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Applicant knowingly and voluntarily relinquishes all rights to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Applicant affirmatively agrees that this Consent Agreement shall be irrevocable. Applicant acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke acceptance of the Consent Agreement or make any modifications to the document regardless of whether the Consent Agreement has been signed by the Executive Director. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

4. Applicant understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against it.

5. Applicant understands this Consent Agreement deals with a Board Complaint involving allegations of unethical conduct against Applicant. The investigation into these allegations against Applicant shall be concluded upon the Board's execution of this Consent Agreement.

6. Applicant acknowledges and agrees that the acceptance of this Consent Agreement is solely to settle this Board matter and the granting of permit applications and the resolution of unpermitted activity referenced in this Consent Agreement and does not preclude the Board from instituting other proceedings as may be appropriate now or in the future.

7. Applicant understands that, except as provided in this Consent Agreement regarding the granting of permit applications and the resolution of unpermitted activity referenced in this Consent Agreement, this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

8. Furthermore, and notwithstanding any language in this Consent Agreement, this Consent Agreement does not preclude in any way any other state agency or officer or political subdivision of this state from instituting proceedings, investigating claims, or taking legal action as may be appropriate now or in the future relating to this matter other matters concerning Applicant, including violations of Arizona's Consumer Fraud Act. Applicant acknowledges that, other than with respect to the Board, this Consent Agreement makes no representations, implied or otherwise, about the views or intended actions of any other state agency or officer or political subdivision of the state relating to this matter or other matters concerning Applicant.

9. This Consent Agreement is effective only when signed by the Executive Director. If this Consent Agreement does not become effective it is withdrawn and shall

be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that if this case proceeds to hearing, Applicant shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

11. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

12. Applicant understands that any violation of this Consent Agreement constitutes unethical conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(A)(16) and A.R.S. §32 – 1927.02(A) (1).

13. The parties understand and agree that Portable Document Format and facsimile copies of this Consent Agreement including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

14. Applicant agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

ACCEPTED AND AGREED BY APPLICANT

Dated: 4/12/2024

On Behalf of
Stryker Sustainability Solutions, Inc.
and Howmedica Osteonics Corp.

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Stryker Sustainability Solutions, Inc. operated as a resident virtual manufacturer at two locations in the state of Arizona and Howmedica Osteonics Corp. operated as a wholesaler at one location in the state of Arizona. These three locations are not currently permitted in the state of Arizona.

3. During an inspection of a third Arizona-based Applicant location that held a permit but required a different type of permit, the Board identified potential unpermitted activity involving a different location and opened an investigation.

4. Applicant, through counsel, informed the Board that in fact, it was likely that several additional locations required permits. Applicant was already in the midst of a multi-year enterprise-wide project to rectify this oversight and voluntarily identified to the Board those locations within Arizona that Applicant believed required permitting.

5. In total, Applicant filed 28 permit applications with the Board and met with the Board on multiple occasions to discuss an efficient and orderly process to resolve all unpermitted activity at Applicant's locations that held or sought new permits.

6. Applicant acknowledges that it has manufactured and sold numerous devices from and into Arizona from unpermitted locations.

7. Applicant has 28 pending permit applications with the Board, which include administratively incomplete applications and applications that are substantively complete and ready for issuance. Three of these pending permit applications related to operations located within the State of Arizona.

CONCLUSIONS OF LAW

1. The Board asserts jurisdiction over the subject matter and over Applicant pursuant to A.R.S. § 32-1901 *et seq.*

2. The Board may deny a permit to an Applicant who has engaged in unethical conduct. A.R.S. § 32-1927.02(P).

3. The conduct and circumstances described above provide grounds for Board to impose discipline under A.R.S. §32-1927.03 which provides, that a person that resides in any other jurisdiction and that sells a prescription-only drug or device, within or into this state shall hold a valid board-issued permit and which allows the Board to impose a civil penalty for unpermitted activity.

ORDER

Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY ORDERED THAT:

1. Stryker Sustainability Solutions, Inc. and Howmedica Osteonics Corp. shall jointly pay to the Board as a civil penalty the sum of Three Hundred Seventy-Five Thousand Dollars ($375,000/$125,000 per unpermitted location in this state). The civil penalty shall be paid in full to the Board within **Ninety (90) days** of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.

2. **IT IS FURTHER ORDERED, that the Board, through its Executive Director shall immediately grant and issue permits for all substantively complete applications and shall without delay, grant and issue permits for all applications that Applicant shall cause to be substantively completed or resubmitted to the Board in compliance with this Consent Agreement, subject to the following:**

   a. **The Board shall not grant any applications until such time Applicant pays the civil penalty as set forth above and any applicable permit fees.**

b. **The Board shall not grant any application until it has determined through its Executive Director, that the application is substantively complete and that the Applicant has met the minimum requirements for the permit.**

c. **The Board shall not consider any unpermitted activity at any location in deciding whether an application is administratively or substantively complete and shall not deny any application or pursue any other available remedy on the basis of unpermitted activity at any location before the effective date of this Consent Agreement.**

d. For each non-resident location, the Board shall issue a non-disciplinary advisory letter for unpermitted activity.

e. Upon Applicant's execution of and compliance with the terms in this consent agreement, including payment of the amount set forth in paragraph 1 above, all matters arising out of or made in connection with this consent agreement shall be fully resolved.

3. **By entering into the Consent Agreement, Applicant waives its right to appeal. In addition, the Board may seek further remedies as permitted by statute.**

4. With respect to the approximately twenty-five (25) various permit applications pending before the Board filed by or on behalf of Stryker Corporation or its subsidiaries, the parties acknowledge that the applications are in various stages of review by Board staff. Some applications are incomplete awaiting the receipt of additional information. Other applications were administratively closed because requested information was not timely received. Applicant has stated its intention to refile those applications and have all of its facilities come into compliance with Arizona law. **The parties agree that all applications that are otherwise complete and have met the**

requirements for licensure, shall be approved and the permits granted with Advisory Letters issued accordingly with each approved application.

5. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.

DATED this 16th day of April, 2024.

ARIZONA STATE BOARD OF PHARMACY

By: Kam Gandhi
KAMLESH GANDHI, PharmD
Executive Director

ORIGINAL OF THE FOREGOING FILED
this 16th day of April, 2024, with:

Arizona State Board of Pharmacy
1110 W. Washington St, Ste 260
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED BY
ELECTRONIC & REGULAR FIRST-CLASS MAIL
this 16th day of April, 2024, to:

Stryker Sustainability Solutions, Inc.
Attn: Marissa Richmond
4675 E. Cotton Center Blvd., Ste. 167
Phoenix, AZ 85040
marissa.richmond@stryker.com

Howmedica Osteonics Corp.
Attn: Cameron Caller
1023 Cherry Road
Memphis, TN 38117
cameron.caller@stryker.com

COPY OF THE FOREGOING E-MAILED
this 16th day of April, 2024 to:

Mark Boesen
Michael Raine
Boesen & Snow Law
8501 E. Princess Dr., Ste. 220
Scottsdale, AZ 85255
MBoesen@BSLawUSA.com
MRaine@BSLawUSA.com

COPY OF THE FOREGOING E-MAILED
this 16th day of April, 2024 to:

Jeanne Galvin Seth T. Hargraves
Assistant Attorneys General
2005 N, Central Ave, SGD/LES
Phoenix, Arizona 85004-1592
Attorney for the State
LicensingEnforcement@azag.gov

JM Itchell

Doc #11915034

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

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: NJ

Parent Company (if any): Stryker Corporation (SYK)

Corporation Name: Howmedica Osteonics Corp

Mailing Address: 325 Corporate Dr

City: Mahwah State: NJ Zip: 07430

Telephone: 269-385-2600 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

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

Howmedica Osteonics Corp

Facility Name

Jimmy Pan

Print Name of Authorized Person Submitting Application

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

10APR2024

Date

Board Use Only	Date Received: 6/11/24	Amount: $1000-CK 12713

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing
New Search Back To Search Results

Establishment:
HOWMEDICA OSTEONICS CORP
Business Trade Names:
(1) Stryker (2) Stryker Orthopaedics

325 CORPORATE DR.
MAHWAH, NJ 07430
Registration Number: 2249697
FEI Number*: 3003070421
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Dervillia Murphy
Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430
Phone: 201-8315113

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

verified M.H 5/13/24

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishr
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishr

Page Last Updated: 05/13/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance
State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

Links on this page:

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishr
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishr

Officer List with Percentage Owned

	Name	Title	Role	Percent Owned
Howmedica Osteonics Corp.	Cedron, Andres	Vice President & Corporate Secretary	Officer	0%
Howmedica Osteonics Corp.	Stiles, Spencer S.	Director & President	Officer	0%

Please note that Andres Cedron left the company unexpectedly in April 2024. A replacement for his role has yet to be made.

Good Standing - Incorp State

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

HOWMEDICA OSTEONICS CORP.
0100051105

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on November 16, 1977.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 1st day of May, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6153139822

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

Home State License

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0750854

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

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

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

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

325 CORPORATE DR MAHWAH, NJ 07430-
165 E 9TH AVE RUNNEMEDE,NJ 08078-
480 SOUTH DEAN ST ENGLEWOOD, NJ 07631-

Reg. No.
5001559

HOWMEDICA OSTEONICS CORPORATIO
325 CORPORATE DR
MAHWAH, NJ 07430-

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

EXPIRES: January 31, 2025

Establishment Copy

Howmedica Osteonics Corp
Ownership List with Percent Owned

Stryker Corporation	100%

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Stryker Corporation & Subsidiaries 1941 Stryker Way Portage MI 49002 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH)	N/A		AOS				
A	If yes, describe under DESCRIPTION OF OPERATIONS below			MWXS31274524 Excess WC - MI SIR applies per policy terms & conditions	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

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

FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570103677315

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Howmedica Osteonics Corp — MDEG License # (if applicable): Not applicable

Physical Address: 325 Corporate Dr

City: Mahwah — State: NJ — Zip: 07430

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

City: _____ — State: _____ — Zip: _____

Telephone: 201-819-6302 — Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Jimmy — Middle: Yu — Last: Pan

Alias(es, nicknames, name changes, etc.): not applicable

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

Mailing Address: [redacted] Johnson Ave

City: Dumont — State: NJ — Zip: 07628

Telephone: 201-819-6302 — Email: statelicensing1@stryker.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
New Jersey Institute of Technology		2011 - 2012	
Address	**City**	**State**	**Zip**
323 Dr Martin Luther King Jr Blvd	Newark	NJ	07103
Diploma/Degree obtained, if any			
MS Biomedical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Johns Hopkins University		2007 - 2011	
Address	**City**	**State**	**Zip**
3400 N Charles St	Baltimore	MD	21218
Diploma/Degree obtained, if any			
BS Biomedical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Western High School		10/03 - 05/07	
Address	**City**	**State**	**Zip**
1200 SW 136th Ave	Davie	FL	33325
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2017 - present	[redacted] ohnson Ave	Dumont	NJ	07628
12/2016 - 12/2017	[redacted] Willow Ct	Cranbury	NJ	08512
9/2015 - 12/2016	[redacted] Slater Ave Apt. 104 ~~9/2015 - 12/2016~~	Fountain Valley	CA	92708
09/14 - 09/15	[redacted] Tustin East Dr. Apt. 37	Tustin	CA	92780
01/14 - 09/14	[redacted] Fox Run Dr.	Plainsboro	NJ	08536

an

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

Business Name			From - To (MM/YY – MM/YY)	
Howmedica Osteonics Corp.			12/2016 - present	
Business Address		**City**	**State**	**Zip**
325 Corporate Dr.		Mahwah	NJ	07430
Phone	**Title**		**Number of Employed Hours**	
201-819-6302	Sr Project Manager		14,000+	
Description of Duties				
See attached resume				

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

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

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

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

Continue on next page if additional space is needed.

I, Jimmy Pan, certify that as the MDEG Administrator for

Howmedica Osteonics Corp.,

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

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

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

Jimmy Yu Pan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

16 MAY 2024
Date

Board Use Only	Date Received:

Jimmy Pan

jimmy.pan@stryker.com 201-819-6302

Stryker
325 Corporate Dr. Mahwah, NJ 07430
0% Ownership

Senior Project Manager *11/2021 - Present*

- Managing team of 2 contingent QEs in product/manufacturing transfers and sterile packaging material changes
- Leading site QE team for sustaining business operations across 12+ manufacturing cells, coordinating with NC/CAPA, change control and cross-divisional RA/QA, product engineering/product development partners
- Coordinating across multiple organizations for placement and monitoring of FG product holds for investigations
- Supervising complaint investigation activities for plant operations for timely closure and escalations
- Overseeing implementation of bespoke concession process and QA resources to modify product markings to allow its sale in CE markets
- Leading MDSAP & other regulatory audit preparation across manufacturing and quality operations; coordinate audit role staffing, logistics planning, participant training & development, backroom/front room communication and SME for applicable areas
- Co-launched Asian Community Empowerment employee resource group as Membership Chair aimed at promoting Diversity, Equity, and Inclusion company initiatives

Staff Quality Engineer *04/2020 – 11/2021*

- Day-to-day quality support for process focus areas in sterile & non-sterile final cleaning, packaging & labelling for orthopaedic and craniomaxillofacial product lines
- Oversaw site quality operations of Emergency Relief Beds assembly during Covid-19 response with rapid (5 day) process development. Devised/optimized production throughput based on floor space & safety requirements, risk-based quality inspection criteria, operator training, production metric tracking and vendor defect trending
- Translated changing regulatory requirements including Brexit notified body transition & EUMDR implementation for manufacturing constraints to minimize service disruptions
- Lead investigator for plastic liner products & packaging manufacturing related complaints

Senior Quality Engineer *03/2019 – 04/2020*

- Supported multiple ISO 8 controlled environments, on-site gas plasma sterilization operations and contract vendor gamma and EtO sterilization modalities and product final release processes
- Lead auditor for internal audits of multiple plant value streams and other regional sites
- Organized QA organization engagement events and cross-functional sporting activities

Quality Engineer *From hire on 12/19/2016 – 03/2019*

- Quality representative for multiple metal and plastic barstock manufacturing cells in machining hip, knee and shoulder replacement devicess
- Created human error reduction program leading to consecutive ~40% reductions human factor NCs year over year
- Owned and reviewed NCs & CAPAs for compliance to regulations while ensuring thorough and accurate investigations, root cause determinations and final product dispositions
- Initiated revamped process for new team member onboarding and cross training

Seaspine
2 Goodyear, Irvine, CA 92618 1-888-942-8698

Manufacturing Engineer *09/2014 – 11/2016*

- Manufacturing engineering team lead for sustaining day-to-day business operations in equipment and packaging design validations, NC/CAPA ownership in aseptic processing environment of human & bovine tissue devices
- Developed supplier relations for designing and machining of custom tooling & fixtures

---

New Jersey Institute of Technology – *M.S. Biomedical Engineering* *2011 - 2012*
323 Dr Martin Luther King Jr Blvd, Newark, NJ 07102

Johns Hopkins University – *B.S. Biomedical Engineering* *2007 - 2011*
3400 N. Charles St., Baltimore, MD 21218

ISO 13485 Lead Auditor (40 hrs)

an

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Howmedica Osteonics Corp

Pharmacy/Wholesaler License # (if applicable): Not applicable

Physical Address: 325 Corporate Dr

City: Mahwah State: NJ Zip: 07430

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

City: State: Zip:

Telephone: 201-819-6302 Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Jimmy Middle: Yu Last: Pan

Alias(es, nicknames, name changes, etc.): Not applicable

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

Mailing Addres[redacted] Johnson Ave

City: Dumont State: NJ Zip: 07628

Telephone: 201-819-6302 Email: statelicensing1@stryker.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
New Jersey Institute of Technology		2011 - 2012	
Address	**City**	**State**	**Zip**
323 Dr Martin Luther King Jr Blvd	Newark	NJ	07103
Diploma/Degree obtained, if any			
MS Biomedical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Johns Hopkins University		2007 - 2011	
Address	**City**	**State**	**Zip**
3400 N Charles St	Baltimore	MD	21218
Diploma/Degree obtained, if any			
BS Biomedical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Western High School		10/03 - 05/07	
Address	**City**	**State**	**Zip**
1200 SW 136th Ave	Davie	FL	33325
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2017 - present	[redacted] Johnson Ave	Dumont	NJ	07628
12/2016 - 12/2017	[redacted] Willow Ct	Cranbury	NJ	08512
9/2015 - 12/2016	[redacted] Slater Ave Apt 104	Fountain Valley	CA	92708
09/2014 - 09/2015	[redacted] Tustin East Dr. Apt. 37	Tustin	CA	92780
01/2014 - 09/2014	[redacted] Fox Run Dr.	Plainsboro	NJ	08536

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

Business Name: Howmedica Osteonics Corp			From - To (MM/YY – MM/YY): 12/2016-Present
Business Address: 325 Corporate Dr.	City: Mahwah	State: NJ	Zip: 07430
Phone: 201-819-6302	Title: Sr Project Manager		Number of Employed Hours: 14,000+
Description of Duties: See attached resume			

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

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

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

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

Continue on next page if additional space is needed.

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

I, Jimmy Pan, **certify that as the designated representative for** Stryker - Howmedica Osteonics,

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

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

Jimmy Pan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10APR2024

Date

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

Jimmy Pan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10 Apr 2024

Date

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

State of New Jersey, ss. County of Bergen

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

Original Signature

10 Apr 2024

Date

Subscribed and Sworn to before me this 10 day of April.

Notary Public Signature

JULIA BALLY
Notary Public, State of New Jersey
My Commission Expires 05/24/2027

(Seal)

Nevada Section 2: History of Company

Qualifiers:

3: Applicant does not manufacture/distribute pharmaceuticals.

4: Applicant does not manufacture/distribute controlled substances.

Howmedica - 325 Corporate Dr Mahwah,NJ
Employee List

Abby Johnson
Abdul-Nafea Syed
Abhishek Trivedi
Adam Bastian
Afreen Khoja
Ahmad Faizan
Aileen McGovern
Akeem Downer
Alex Syzonenko
Alexa Hacopian
Alexandra Valentino
Alexis Culhane
Alissa Sellers
Allison Byrne
Alyssa Clymer
Alyssa Pennell
Amanda LoMonaco
Amith Nayak
Amy Dellatte
Ananthkrishnan Gopalakrishnan
Andrea Coppolecchia
Andrew Dumont
Andrew McKenzie
Andrew Min
Andrew Moore
Andrew Pappalardo
Andrew Wheeler
Andrew Wong
Andy Nedilsky
Anika Agnihotri
Anne Edwards
Anthony Cambria
Anthony Habib
Anthony Urciuoli
Antonio Gil
Arantxa Negit
Ariana Layne
Arshad Mulla
Asher Odero
Ata Babazadeh Naseri
Austin Rutz

Jose Gutierrez
Sonia Areiza
Nate Thompson
Realito Magpayo
Muhamet Vinca
Omar Gutierrez
Joumaul Fraser
Josue Mendez
Susan Perez
Eddie Montani
Thomas Flanagan
Antoine Cunningham
Joanovic Nicolas
Gregory Kleaver
Nirva Cedeno Bertrand
Luis Fernández Santana
Yameli DejesusOrtiz
Isaac Acquah
Carlos Villagomez
Kennis Acosta Cabrera
Tariq Francis
Anthony Bravo
Andrew Rivelli
Justin Molina
Ramon Tiburcio Quezada
Horacio Garcia Granados
Pablo Perez Gracia
Sergio Vargas Ruiz
Nicholas DiNapoli
Pedro Estevez
Moayad Abdullah
Dipak Patel
Cameronn Parker
Abdalah Zidan
Al Mahmud Rahi
Iz Dogjani
danilo philogene
Jeremy Blood
Gohar Khan
JAVOHN MARTIN
Magda Rusiecki

Awilda Inoa
Barbara Jamgochian
Becky Addy
Behzad Farshid
Bernard Liebeskind
Beth Parks
Bhanu Vemula
Bill Bergmann
Binu Balakrishnan
Boguslawa Wuennenberg
Brad Curtis
Bradley Nolan
Brandon O'Donnell
Brian Altman
Brian Brandell
Brian Lauro
Brian McCrone
Brian Reilly
Brian Smyth
Brian Van Ness
Brianna Hulbert
BriAnna Puma
Bridget Bollinger
Brinda Badwe
Brittany Meerholz
Brooke Hannaford
Cailin Morris
Cameron Erber
Camille Aveni
Cara Sullivan
Carlos Aponte
Carlos Collazo
Carlos Jimenez Navarrete
Caroline Atkinson
Caroline Bohlin
Caroline Weinberg
Carrie Hopson
Catherine DeWitt
Catherine O'Connor
Celeste Vasil
Chau Ngo
Chelsea Frattari
Cheryl Deloughery
Cheryl Griscavage

Stephen Scarlett
Sidney Rozier
Laith Abdallah
Kenneth Bronstein
Lisseth Mitten Ductran
Andrew Pavkovitch
Waleed Mohamed
Nikitas Christodoulou
George Wilson
Konstantinos Perselis
Steven Soto
Gregory Sajous
Suhel Arman
Kazuhiro Dayo
Terence Nish
Vanas Aryeequaye
Joshua Gutierrez
FRANKLIN CRUZ
Ebel Checo Jimenez
Adam Teif
Angel Sanchez
Ikechukwu Nwoga
Isaac Oquendo
Ru Cai
Ben Bamfo
Sunday Adelaja
Raudy Calderon
NAZMUL ISLAM
Ed Villa
Francisco Portorreal
Sayed Haque
Michael Kearns
Ismail Savas
Hitkaran Grewal
Givenchy Buly
Mushtaq Soomro
Alfred Koomson
Christian Ducut
Michael Favocci
Amelito Borromeo
Janet Paguirigan
Oshane Green
Mohammed Salami
Foyzul Islam

Cheryl Liu
Chin Chiu
Chris Ellam
Christina D'Anjou
Christina DiCesare
Christina ONeill
Christina Rogers
Christine Delaney
Christine Ehlers
Christine Loyas
Christopher Heffernan
Christopher Niel
Christopher Roger
CHRISTOPHER SLIMAK
Christopher Zak
Cole Garabed
Collin Desens
Connor Tighe
Conor McGuire
Cory Sahanas
Cristian Corui
Damon Servidio
Dan Brannigan
Dan Matrisciano
Dan Scholl
Dan Zadow
Daniel Barcenas
Daniel Kubat
Daniel Pham
Daniel Rosenthal
Daniel Weller
Danielle Tedesco
Danielle Wolfe
Daniil Gregoriev
David Heard
David Wartel
David Weissman
Deba Roy Chowdhury
Debbie Brown
Denise Daugert
Denise Trella
Dervillia Murphy
Donna D'Alessio
Donna Russell

jan hettema
Shim Campbell
Liton Chowdhury
Michael Obeso
Steven Nunez
Edwin Bonano
Ian Gray
Ye Hnin
Trevor Wilson
Jason James
Victor Balbi
Samantha Levy
Jeffrey Montesino
Oduwa Usiomoifo
Suzan Ishak
jose collado
DAVID GARCIA
Elizabeth Surowiec
Loredana Speranza
Juan Polanco
JHON SAAVEDRA ROQUE
Thomas Kallergis
Donald Simpson
Gloria Cepeda
Matthew Spagnoletti
Sumaia Ferdous
Yenfris Pagan Ruiz
Camron Parker-Taylor
Narcisa Delgado Rodríguez
Rasheedat Egunlaje
Serhiy Hrynyak
Matthew Cimaglia
Jacob Janvier
Manuel Fernandez-Santos
John Mannah
Jeremy Lantigua
Nicholas Asamoah
Robert Gault
Eric Rodriguez
Lucyna Krawontka
Robert Slazyk
Elmer Obeso
Diana Espinosa Rojas
Christopher Newell

Drew Bone
Duane Hoogerhyde
Eddy Iturbide-Huerta
Edward Klecha
Edwin Merchan
Efrat Rosmarin
Elena Doce
Eli Slavin
Elisabeth DeWitt
Elizabeth Gonzales
Elle Macari
Emily D'Angelo
Emily Hampp
Emily Sailer
Emily Santosuosso
Enk Zgjani
Enos Ntombura
Erika Corbin
Erin Hinnegan
Eswar Pinnamaneni
Evan Cartwright
Evan Thomas
Evelyn Yang
Everett Hannah
Fabiano Pace
Fallon Wald
Felix Salcedo
Fengling Shi
Francois Dao
Frank Stroker
Frederick Treslar
Gabriel Geraldo
Gabriella Doran
Garrett Joyal
Gelsey Patrick
Gianna Scire
Gilbert Agyeman
GINA Ruppert
Glenn Schneider
Greg Boggis
Greg Longabucco
Gregory Pepe
Guilly Mendoza
Guy Nicaise

Jesus Fernandez
Octavio Fernandez
Tadeusz Nowicki
Luis Santiago
Brian Pariona
Max Del Prado
Francisco Apolinario - Pena
Deoraj Ramdin
Victor Rivera
Anna Dluzniewski
Michael Wilson
John Valencia
Kelvin Rojas
Kemar Ramsay
Robert Escolastico
Daniel Ivey
James Yager
Steven Balbi
David Montalvo
Rafael Mora Reynoso
Krystyna Drelich
Angelo Patire
Josue Munoz
George Zea
Flavio Giura
Luis Rodriguez
Mensur Murati
Raphael Avalos
Patrycia Reyes
Gregory Dyer
Carlos Zabala
Krystal Civitano
Diana Castro
Luis Felipe
Florangel Castillo Nolasco
Antonio Scola Jr
Bahar Kocas
Damian Simpson
Pedro Perez Dominguez
Andre Hall
Norka Costa Ferretti
Marleni Burgos Torres
Jose Martinez
Victor Valverde

Haitong Zeng
Haley Hanrahan
Han Wang
Hannah Pacheco
Hector Hernandez
Herbert Goebbert
Ilissa Hamilton
ILYA BORUKHOV
Ivan Herrera
Jackie Rivera
Jaime Toyama
Jaison Kuruvilla
Jake Martin
James Gilligan
Jane Bastian
Jane Guo
Jared Hills
Jarett Michaelson
Jasmine McDuffie
Jaymie Fiebel
Jayvon Blackmon
Jean Amaro
Jeffrey Strumpf
Jenna Schwartz
Jennifer Ahrens
Jennifer Barnes
Jennifer Lopez
Jennifer Lynch
Jennifer Warnke
Jeremy Olsen
Jerry D'Alessio
Jess Abrams
Jesse Bagley
Jesse Cassar
Jessica Cetrangol
Jessica Sethi
Jeyson Mojica
Jianhua Shen
JoAnn Ripoli
Joanna Kleszczewski
Joe Green
Joelle Battista
John Eugenis
John La Barbera

Robert Tachie-Menson
Gennady Bogatyrev
Robert Terrero Perez
Giselle Gonzalez
Jhoana Gomez De Hidalgo
Alejandro Avila Reyes
Robert Germosen polanco
Kevin Fernandez
Armend Murati
Cornelius Wallace
Jason Forney
Sotiris Hondros
David Sunseri
Louis Lopez
Donald Anderson
Evelyn Ynfante
Jake Nouel
Patricia Margarita Nuesi
Alfonso Guerra
Steve Mazur
Cesar Soto
Mahesh Gandhi
Mariusz Radzikowski
Kelman Morris
Luis Lazo
Adeel Awan
Avelino Bernardo
William Moran
James Richardson
Carrington Simmons
Juan Grullon
Artemio Rodriguez
Michael Pinero
Luis Polanco
Andrzej Siomko
Elias Kiame
Luis Vasquez
Miguel Gonzalez
Nathaly Rodriguez
Bruno Molinares
Joseph Lapszynski
Samuel Doe
Peco Milenkovski
Saima Hashmi

John Lynch
John Muth
John Serino
Jonathan Sandler
Jordan Kayal
Jose Quintana
Joseph Michalowicz
Joseph Racanelli
Josh Peterson
Juana Hiciano
Julia Bally
Julia Greenspan
Julia Halligan
Julia Loughren
Julian Dinkins
Julie Youngs
Julissa Monahan
Justin Bernardino
Justin Malaussena
Justin Malone
Justin Moidel
Justin Segal
Justyna Kotowski
Kailey Fitzgerald
Kaitlin Millicker
Karen Ariemma
Karen Ayoub
Karisa Arnhold
Kate Bray
KATIA CARROZZA
Katrina David
Kayla Bistany
Kayla Hobal
Kazi Zunaid
Keenan Hanson
Kelly Ratigan
Kelsey Williams
Kelsy Stetter
Ken Pascale
Ken Richard Agatsuma （我妻 謙リチャード - ｱｶﾞﾂﾏ ｹﾝﾘﾁｬｰﾄﾞ）
Kenneth Trimmer
Kerianne Coulon
Keven Polanco
Kevin Abbruzzese

Ambiorix Ventura
Md Chowdhury
Dawan Ray
Gerald Beauvais
Al Dyer
Sergio Piccininni
Wimel Liz Pena
Mujahid Riyaz
Nathalia Falette Mendez
Eddy Cordova
Leon Johnson
Barbara Gassler
Raymond Paredes
Yissel De La Rosa
Juan Santana
Carlos Ortiz
Enmanuel Henriquez
Yulianne Mejia
Robe Beno
Timothy Rifflard
Adam MacDonald
Keith Plaskon
Juan Gomez
Thomas Moran
Kelly Castillo
Charles Ray
Belal Jallad
Joseph Adjabeng-Ankrah
Dariusz Medrek
Michael Jimenez
Matthew Gorman
Thanh Tram
Lauren Azevedo
Andres Fabregas Polo
Carlos Gonzalez
Joshua Rodriguez
Joaquin E De Moya
Vincent Vilardi
Wellington Moreno de Leon
Han Trinh
Emmanuel Felipe
Recep Colak
Blaine Fernandez
Mark Stella

Kevin Barga
Kevin Froster
Keyla Colon
Kim Chan
Kimberlee Martini
Kimberly Amaba
Kimberly Wylde
Kinaada Albert
Kris Pawelko
Krista Brennan
Kristin Frederiks
Kristine Westenberger
Kunjan Patel
Kyle Price
Laura Celli
Laura Scholl
Lauren DeSimone
Lauren Elaine Massock Chin
Lauren Koederitz
Lauren McCarthy
Lauren Venekas
Lauren Williams
Lawrence Wissman
Leah Allen
Lee Sprung
Lee Wiggins
Lena Halverson
Leo Pavlovsky
Lewis Brown
Lewis Mullen
Ligaya Marquez-Catral
Lily Oakes
Lin Song
Linda Russo
Lisa Kloes
Lisa Sesink-Clee
Lori Andreoni
Lori Merriam
Loriann Russo
Loucas Nestoros
Luca Geralds
Luis Rosario
Maciej Cherkowski
Madison Leiman

Kennedy Everett
Vaughn Bailey
Mitko Gadgev
Stephanie Salinas
Stanley Bogard
Dwayne Lee
Katarzyna Kubacka
Gabriel Castro
Hasan Abzakh
HUSNAIN Ishtiaq
Divan Rojas
Devor Lebert
Alan Clearwater
Jose D Guzman
Wilson Ynfante
Vishal Rana
Lenny Duran
Mario Pacheco
Frank Bakovic
Asad Naqvi
Jim Graves
Joseph Nagy
Alvaro Flores
Ivan Abanto
Martin Doria
Terence Carter
John Muir
Wolf Bravo
Helmut Permunian
McNicky Pierre Louis
Angel Adames
Umit Arat
James Polanco
Carlos Perez
Roberto Adames Cespedes
mohd obikh
Samuel Francois
Dharmesh Bhagat
Michael Oggenfuss
Justin Guerrero
Wander Henriquez
Harpreet Dhaliwal
Elizabeth Ortiz
Sultan Tipu

Madison Ouellette-Hays
Manny Punla
Manoshi Bhowmik-Stoker
Manuel Morales
Marc Esformes
Margaret Klippel
Maria Garrido
Maria Troiani
Maria Wygonik
Marisol Santiago
Marissa McAndrew
Marissa Puccio
Mark Kansburg
Matt Greenberg
Matthew DaSilva
Matthew Demers
Matthew Diaz
Matthew Fariselli
Matthew Fiebel
Matthew Jenkins
Matthew Nicosia
May Ling Brantman-Djurasevic
Mayur Thakore
Megan Weyer
Meghan Fullman
Meghan Vellotti
Melanie Caba
Michael Agostin
Michael Barkachy
Michael Bogart
Michael Cordero
Michael DeLuise
Michael Ferko
Michael Goodfriend
Michael McGovern
Michael Shabelman
Michael Tartaglia
Michele Alshouli
Michelle Kim
Michelle O'Malley
Michelle Pena
Mike Cruikshank
Mike Florentino
Mike Mills

Gaby Chumpitaz
Carlene Contreras
Julio Urena
Crismeidy Bernard
Joseph Lee
Reggie White
Chanda Sum
Salman Yousaf
Justin ODonnell
Yash Rana
David Rose
Tanya Choksi
Cora LoPresti
Dilipkumar Shah
Donald Dries
Valentine Oleschuk
Samy Amar
Shawn Daly
Kenneth Chiu
Frank LoPiccolo
Monal Amin
Julian Colón
Ashley Abanilla
Samantha Tornillo
Alexander Belik
Mykola Kolomiichuk
Mike Zheng
Jacob Klemmer
Brooke Leiser
Fady Elgindy
Tonni Hasan
Meagan Irish
Steven Giraldo
Dariel Stack
William Bongiorni
Jessica MacDonald Alagna
Andres Paez
Nicole Tacopina
Rachna Patel
Richard Ortiz
Karina Yeh
Tariq Eatman
Cristobal Rivera
Cesar De La Cruz

Mohit Jetti
Mohsin Javid
Molly Walker
Myrian Bright
NADIA HADDAD
Natalia Gonzalez
Natalie Fitzpatrick
Neel Patel
Neesa Serritella
Nelson Arnold
Niamh Grano
Nicholas LaVigna
Nick Plaskon
Nick Vitiello
Nicolas Bethoux
Nicole Liddy
Nicole Maceri
Nicole O'Brien
Nikhil Patel
Nikola Kotevski
Nishma Menda
Nora Kdiry
Oliver Jenner
Oronde Carroll
Patricia Brackenbury
Patricia Halsey
Paul Andreasen
Paul Bruchalski
Paul Jahnke
Peter Mousa
Peter Toth
Peter Tulkis
Peter Wellings
Phillip Hughes
Polina Canepa
Qing-Qing Qiu
Rachel Hazard
Rachel Plaskon
Rafael Baez
Rana Abdallah
Raul Hincapie
Ray Paltooram
Rebecca Moretto
Richard Afflitto

Mark Norman
Leonardo Tello
John Cucinella
Carmen DeVito
Samuel Mukaida
BRIAN ABEL
Dominick Blandino
Keith Brown
Gregorio Frias
Cesar Freeman
Ying Cong Ma
Joseph Caiazza
Gerzain Figueroa
Jennifer Santos
Robert Estevez
Victor Watkins
Christopher Manning
Joseph Luglio
Manuel Nunez
Patrick Giacobbe
Alvin Alameda
Ante Ivankovic
Mehul Tailor
Noralin Tavarez
Rudolf Mallari
Tomasz Bazel
Mark Grochola
Lojza Martinoski
Mercy Thandi
Carline Louis Jean
Raechel Cordova
Stasia Hrab
Bernadetta Szproch
Joanna Such
Eileen Kadian
Jacqueline Mercado
Thierry Pierre
Theresa Burnett
Natalie Ramirez
Ted Laforest
Patricia Cooper
India McEachin
Josue Santiago
Abigail David

Rick Roberti
Rita Koremblum
Robert Cheng
Robert Davignon
Robert Sloan
Robert Tust
Roxana Sanderson
Ryan Anderson
Ryan Chan
Ryan Freitag
Ryan Sokolow
Sabrina Cristofaro
Sagar Chadha
Sally LiArno
Samantha Rivera
Santos Ortiz
Sarah Bell
Sarah Imami
Sarah Mastrandrea
Scott Logan
Scott Taylor
Sean Carmody
Sebastian Martell
Shammodip Roy
Shaneek Anderson
Shannon Collins
Sharon Gaukler
Shaun George
Sheldon Nidhan
Shikha Khandelwal
Shilpa Donde
Shulin He
Sidney Ortiz
Simon Chon
Sion Aronoff
Sonia Donde
Sophie Hatcher
Spencer Englander
Stephanie Hassler
Stephanie Masotti
Stephen Beckmann
Stephen DiMora
Stephen Lomicky
Stephen Slater

Ana Duarte
Elizabeth Ambrosio
Jeremiah Solon
Evelyn Abreu
Kimberly Jarrett
Esther Mendez
Gladys O Monsalve
Lananh Nguyen
Ava Elliott
Jinette Garcia
Gineiri Acevedo
Jackie Milenkovska
Melissa Parra
Yennifer Fermin Sanchez
George Ashianor
Kenibel Lopez
Iwona Lubecki
Maria Peralta Rodriguez
Catalina Giraldo Cano
Lizbeth Peralta Basurto
ZUBAIR KHAN
Trudy Ann Ivey
Keisy Martinez
Laura Ramirez
Celeste Lopez De aza
Nicaurys Garcia calvo
Yuderqui Castillo infante
Achiaa Acheampong
Isaac Cuello
Jimmy Espinal
Antonio Gonzalez
Anyi Diaz
Magdeline Rodriguez
Camille Mitchell
Jacqueline Fuentes Tapia
Daniela Cuevas
Aida Carnero
Anthony Rodriguez
Jawad Qureshi
Lucas Bell
Marek Sawicki
Laura Regan
Mario Rojas
Sinar Dishack

Steven Buell
Steven DelMauro
Steven Geraghty
Steven Primiano
Sumbul Khan
Susan Raser
Suzanne Neuschwanter
Talia Grecco
Tanvi Gehani
Tara Margulies
Tara Rudrapatna
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

OR

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

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics, the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,840	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,188	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2018
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement, changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,103	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	$ 3,888	$ 2,841	$ 2,584	$ 2,223	$ 2,713
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	$ 3,673	$ 2,683	$ 2,281	$ 1,954	$ 2,562
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,988	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

Dollar amounts in millions except per share amounts or as otherwise specified.

4D

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: K2M, Inc

Physical Address: 600 Hope Parkway, SE

City: Leesburg State: VA Zip: 20175

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 571-643-8547 Website: www.stryker.com

Name of Designated Representative (DR): Megan Carnes

Licensing Company Email: statelicensing1@stryker.com DR Email: megan.carnes@stryker.com

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

April 2, 2024
Date

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

Name: Not Applicable-no pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): K2M Holdings, Inc and then publicly traded Stryker Corporation (SYK)

Corporation Name: K2M, Inc

Mailing Address: 600 Hope Parkway, SE

City: Leesburg State: VA Zip: 20175

Telephone: 269-385-2600 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

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

K2M, Inc

Facility Name

Megan Carnes

Print Name of Authorized Person Submitting Application

Megan Carnes

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

April 2, 2024

Date

Board Use Only	Date Received: 6/4/24	Amount: $1000-ck 12696

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
K2M, INC.
600 Hope Pkwy SE
Leesburg, VA 20175
Registration Number: 3004774118
FEI Number*: 3008599177
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romance Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Oonagh Lahiff
2 Pearl Ct
Allendale, NJ 07401
Phone: 001-201-8243302

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

√ Verified M.H 6/6/24

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm
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Page Last Updated: 05/13/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "K2M, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "K2M, INC." WAS INCORPORATED ON THE TWENTY-EIGHTH DAY OF JANUARY, A.D. 2004.

Jeffrey W. Bullock, Secretary of State

3757904 8300

SR# 20241774490

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

Authentication: 203377120

Date: 05-01-24

Officer List with Percentage Owned

	Name	Title	Role	Percent Owned
K2M, Inc.	Cedron, Andres	Vice President & Corporate Secretary	Officer	0%
K2M, Inc.	Stiles, Spencer S.	Director & President	Officer	0%

Please note that Andres Cedron left the company unexpectedly in April 2024. A replacement for his role has yet to be made.

K2M, Inc.
Ownership List with Percent Owned

K2M Holdings, Inc.	100%

Virginia Department of Health Professions
An official website Here's how you know

Find a Commonwealth Resource

Virginia Department of Health Professions
License Lookup

Current as of 05/13/2024 13:48

License Information

License Number	0216000200
Occupation	Warehouser
Name	K2M, Inc.
Address	Megan Carnes 600 Hope Parkway SE Leesburg, VA 20175
Initial License Date	05/12/2023
Expire Date	02/28/2025
License Status	Current Active
Additional Public Information*	No

Back to License Lookup Result

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

** "Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.H of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.*

Back to License Lookup

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

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

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

PRODUCER
Aon Risk Services Central, Inc.
MSC#17382
Aon
PO Box 1447
Lincolnshire IL 60069 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 FAX (A/C. No.): (800) 363-0105
E-MAIL ADDRESS:

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

INSURED
Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER							
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A		AOS				
A	(Mandatory in NH)			MWXS31274524	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			Excess WC - MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

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

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570103677315

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600 Hope
Carnes

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG K2M, Inc. MDEG License # (if applicable) Not applicable

Physical Address 600 Hope Parkway, SE

City Leesburg State VA Zip 20175

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

City _____ State _____ Zip _____

Telephone 571-643-8547 Website www.stryker.com

Licensing Company Email statelicensing1@stryker.com

Section 2: Personal Information

First Megan Middle Elizabeth Last Carnes

Alias(es, nicknames, name changes, etc.) Megan Elizabeth McMullen

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

Mailing Addres[redacted] Moore Place

City Leesburg State VA Zip 20175

Telephon[redacted] Email statelicensing1@stryker.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Virginia		2006 - 2008	
Address	City	State	Zip
PO Box 4000203	Charlottesville	VA	22904
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Loudon County High School		1999 - 2004	
Address	City	State	Zip
415 Dry Mill Road, SW	Leesburg	VA	20175
Diploma/Degree obtained, if any			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/2015 - Present	[redacted] Moore Pl	Leesburg	VA	20175
From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/2009 - 7/2015	[redacted] Shadow Terrace	Leesburg	VA	20176
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
K2M, Inc.			2008 - Present	
Business Address		**City**	**State**	**Zip**
600 Hope Parkway, SE		Leesburg	VA	20175
Phone	**Title**		**Number of Employed Hours**	
571-643-8547	Manager, Quality Assurance		31,000+	
Description of Duties				
See attached resume				

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

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

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

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

Continue on next page if additional space is needed.

arnes

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

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

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

Provide explanation below:

May Cano

Original Signature (electronic, copies or stamps not accepted)

May 6, 2024

Date

arnes

I, Megan Elizabeth Carnes, certify that as the MDEG Administrator for

K2M, Inc.,

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

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

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

Megan Elizabeth Carnes
Print Name (First, Last)

Megan Carnes
Original Signature (electronic, copies or stamps not accepted)

May 6, 2024
Date

Board Use Only	Date Received: 5/6/24

MEGAN CARNES

[redacted] Moore Place Leesburg, VA 20175 – [redacted]

EDUCATION

University of Maryland Smith School of Business, College Park, MD 2012
Masters of Business Administration

University of Virginia School of Engineering, Charlottesville, VA 2008
Bachelors of Science: Mechanical Engineering, Minors: Aerospace & Biomedical Engineering

WORK EXPERIENCE

Manager, Quality Assurance, *Stryker, Leesburg, VA* May 2021 – Present

- Lead a high performing team of full time Quality Engineers, Manufacturing Engineers, Engineering/Calibration Technicians and supporting contractors, with 16 reports and foster a culture of excellence and continuous improvement.
- Ensured Key Performance Indicators (KPIs) are achieved and surpassed year over year, focusing on Non-Conformances (NC)/Corrective and Preventive Actions (CAPA), Defects per Million (DPM), Escapes, Product Mix, and Use As Is (UAIs), demonstrating a commitment to quality and efficiency.
- Driven significant quality enhancements that resulted in 63% Escape Reduction in three years as a result of 133 CAPAs Implemented and 400 NCs Executed for internal and external issues.
- Supplier Certification of 1,500 high volume SKUs has led to $240,000 in annual variable head count cost savings.
- Achieved a remarkable 79% reduction in Defects per Million (DPM) from 2018 to 2023 (from 14,802 to 3,125), highlighting a strong focus on quality improvement and defect reduction.
- 12,000 active SKUs are manufactured by Leesburg, with 86% of all product Supplier Certified or with a Streamlined Inspection Plan, allowing for increased product throughput while maintaining the highest quality by making informed decisions based on historical data.
- Manage Supplier Initiated Change Request process that requires knowledge of manufacturing processes, pFMEA, IQ/OQ/PQ, FAI, MSAs, Capability Studies to execute Production Part Approval Process documentation
- Supported the remediation of supplier documentation and inspection plans in response to the European Union Medical Device Regulation (EU MDR), Brexit, and changes in Notified Bodies, ensuring compliance and continuous market access.
- Supported supplier compliance to ISO 19227 for implant manufacturing cleaning, enhancing product safety and quality
- Demonstrated exceptional communication and presentation skills, effectively influencing change among both technical and non-technical stakeholders.
- Excel in a high-urgency environment, leveraging strong analytical and problem-solving skills to manage multiple complex tasks simultaneously with high efficiency.
- Increased Quality Gallup Q12 Engagement scores by 25% in two years.
- Served as the Stryker Women's Network ERG East Region Lead for 2024-2025, overseeing four sites, and as the Spine Lead in 2021-2022, demonstrating leadership in diversity and inclusion initiatives.

Associate Manager, Quality Assurance, *Stryker, Leesburg, VA* February 2019 – May 2021

- Directed a team of eight engineers/technicians overseeing an ISO 13485 and 21 CFR 820 compliant GQO Quality Assurance program for the Leesburg, VA and Allendale, NJ Site.
- Integrated Stryker and K2M Quality Management Systems, including developing processes and procedures for supplier controls, NC/CAPA, validation, inspection and calibration.
- Managed an ASL with over 300 suppliers and supplier processes/products for implants, instruments and biologics.
- Managed Material Review Board that receives on average 2,000 Quarantine Tickets/year.
- Directed the Supplier Initiated Change Request process, ensuring timely and appropriate actions are taken to resolve issues with minimal business impact, thereby maintaining continuous supply chain efficiency.
- Achieved a 98% reduction in UAIs through strategic internal process improvements, ensuring comprehensive communication with suppliers and prompt resolution of issues, significantly enhancing operational efficiency.
- Created and implemented a Quality engagement program that includes a monthly Most Valuable Person (MVP) program with peer-to-peer nominations, fostering a culture of recognition and engagement among the quality team.
- Served as the Spine Events Lead for Stryker Women's Network ERG during 2019-2020.

Supplier Quality Manager, *K2M Inc., Leesburg, VA* August 2018 - February 2019

- Managed a team of three engineers/technicians responsible for leading the K2M Leesburg Supplier Quality program and executing associated systems, processes, programs/initiatives, practices, and metrics for ensuring and improving overall Supplier Quality performance for over 50 Contract Manufacturers and OEMs.

- Fostered effective collaboration between supply chain management, quality control, engineering, R&D, and regulatory departments to set and enforce supplier quality and performance guidelines.
- Spearheaded the supplier audit program, facilitating thorough investigations, reporting on corrective actions (including SCARS and CAPA's) and ensuring timely responses from suppliers.
- Developed risk-based programs and procedures focused on supplier transfers, qualifications, and performance enhancements to increase supplier productivity and efficiency.
- Played a pivotal role in the supplier selection process, evaluating potential partners, and managing the supplier qualification process to ensure high standards of quality and reliability.
- Managed the Supplier Process Review (SPR) process, supervising the validations and qualifications of supplier manufacturing processes to guarantee superior quality in part/component manufacturing.

Senior Project Engineer, *K2M Inc., Leesburg, VA* March 2016 - August 2018

- Manage a team of four full time engineers who develop and maintain over 20 product lines including Interbodies, Corpectomy Cages, Cervical and Lumbar Plates Systems producing over $37 million in 2017 revenue.
- Develop complex implant systems with additively and traditionally manufactured components.
- Coordinate cross functional projects with marketing, quality, regulatory and supply teams to gain 510(k) clearances and CE Markings.
- Review and approve design controls, including drawings, risk management documents per ISO 14971, DHF's, DMR's, traceability matrixes and test reports.
- Developed mentorship program in 2017 for engineers to support co-ops during rotations. Outstanding reviews of the program lead to companywide implementation in 2018.
- Lead monthly trainings with 20+ employees to review legacy systems and share lessons learned.
- Interact and engage with suppliers to improve component assembly processes and implant design.
- Write clinical evaluation reports to support device equivalence and help maintain technical files and essential requirements.
- Interface with surgeons to discuss new product development and feedback from clinical use.
- Five patents issued, four patents pending.

Project Engineer, *K2M Inc., Leesburg, VA* March 2014 - March 2016

- Lead engineer on Interbody, Plates and Standalone Interbodies.
- Assist in writing 510(k)'s for FDA regulatory clearances.
- Manage multiple product lines while simultaneously supporting legacy products.
- Lead and coordinate new product development with marketing and engineer teams.
- Conduct team meetings with K2M Senior Executives and project teams according to ISO and FDA requirements.
- Create and maintain risk management documentation for individual product lines.

Senior Development Engineer, *K2M Inc., Leesburg, VA* May 2011 – March 2014

- Engineer on Interbody, Plates and Standalone Interbodies
- Manage multiple product lines while simultaneously supporting legacy products.
- Work with international teams to develop specific implants and instrumentation for Australia and UK surgeons.
- Test implants to ASTM standards and submit 510(k)'s to the FDA for regulatory clearance.
- Design and perform verification and validation testing on implants/instruments.
- International and Domestic travel to evaluate new implants/instrumentation in surgery and cadavers.
- Communicate and troubleshoot potential challenges with vendors during product manufacturing.
- Coordinated the evaluation launch of the Blue Ridge Hybrid Plate in less than 90 days.
- Support five major product lines that produced over $25 million in revenue.

Development Engineer, *K2M Inc., Leesburg, VA* May 2008 – May 2011

- Support engineer for product lines focusing on plates and interbodies for spine surgery.
- Create complex models and drawings for implants/instruments with SolidWorks utilizing GD&T.
- Updated aging product lines and made rolling changes to adapt to the needs of customers.
- Route drawings for approval in MasterControl, document control software.

Engineering Intern, *K2M Inc., Leesburg, VA* Summers 2005 - 2007

- Assisted Engineers with SolidWorks models and drawings.
- Inspected instruments and implants for quality control.

COMPUTER SKILLS

JDE, SolidWorks, MasterControl, Microsoft Office Suite

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler K2M, Inc

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 600 Hope Parkway, SE

City Leesburg State VA Zip 20175

Mailing Address (if different from physical address) Same as physical address

City _____ State _____ Zip _____

Telephone 571-643-8547 Website www.stryker.com

Licensing Company Email statelicensing1@stryker.com

Section 2: Personal Information

First Megan Middle Elizabeth Last Carnes

Alias(es, nicknames, name changes, etc.) Megan Elizabeth McMullen

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

Mailing Address [redacted] Moore Place Leesburg VA 20175

City Leesburg State VA Zip 20175

Telephone [redacted] Email megan.carnes@stryker.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
University of Virginia			2006-2008	
Address		City	State	Zip
PO Box 4000203		Charlottesville	VA	22904
Diploma/Degree obtained, if any				
Bachelor of Science				
School Name			From - To (MM/YY – MM/YY)	
Loudoun County High School			1999-2004	
Address		City	State	Zip
415 Dry Mill Road, SW		Leesburg	VA	20175
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/24-8/15	[redacted] Moore Pl	Leesburg	VA	20175
7/15-8/09	[redacted] Shadow Terrace	Leesburg	VA	20176
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
K2M, Inc			2008-Present
Business Address	**City**	**State**	**Zip**
600 Hope Parkway, SE	Leesburg	VA	20175
Phone	**Title**	**Number of Employed Hours**	
571-643-8547	Manager, Quality Assurance	31,000+	
Description of Duties			
See attached resume			

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

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

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

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

Continue on next page if additional space is needed.

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

I, Megan Carnes, **certify that as the designated representative for**

K2M Inc,

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

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

Megan Carnes
Print Name (First, Last)

Megan Carnes
Original Signature (electronic, copies or stamps not accepted)

4/2/2024
Date

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

Megan Carnes
Print Name (First, Last)

Megan Carnes
Original Signature (electronic, copies or stamps not accepted)

April 2, 2024
Date

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

State of Virginia, ss. County of Loudoun

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

Megan Carnes
Original Signature

April 2, 2024
Date

Subscribed and Sworn to before me this 2nd day of April 2024

Diana Lee Stonehouse
Notary Public Signature

Diana Lee Stonehouse
NOTARY PUBLIC
Commonwealth of Virginia
Reg. # 7352194
My Comm. Expires June 30, 2026

(Seal)

Name
Aaron Hartlove
Adam Kenny
Adrian Razeghi
Adriana Feraco
Adrienne Stone
Agustin Mata
Ailon Haileyesus
Alecia Moroz
Aleighsa Richardson
Alena Aranda
Alex Sellers
Alexander Artaki
Alexander Lopez
Allison Elkins
Allison Harris
Allison Shaffer
Amanda Wacaster
Amos Sun
Amy Kennedy
Andrew Almaguer
Andrew Clavio
Andrew Parker
Andrew Perkins
Andrew Wortman
Angel Parisi
Angela Dawson
Angelina Cooke
Anna Volanth
Anna-Lynn Sitek
Anne Wele
AnneMarie Valentine
Annie Sun
Antonio Rutherford
Aparna Bharath Kumar
Armand Caron
Arnold Ochoada
Arthur Milner
Ashley Klipp
Atit Patwala
Austin Harrison
Ayomide Ologunja
Bala Gopal Bajjuri
Basma Hassan
BENJAMIN HARPER
Benjamin Shafer
Bob Tokash
Brad Wahl
Brandon Moore
Brian Curry
Brian Gillis
Brian Kunes
Brittany Lang
Bryan Millenacker
Bryon Nicholson
Caity De Angelus

CALEB DIPRETE
Calogero Ramirez
Cami Parrish
Carinne Granchi
Carl Olson
Caroline Weir
Carolyn Zineddin
Casie Castello
Catherine Stone
Cathy Castle
Cesar Cubillos
Chad Drake
Chadwick Lazzell
Charles Okehie
Charlotte Negron Morales
Christal Schwenk
Christina Gossart
Christina Mangione
Christopher Cook
Claudia Mathus
Clint Boyd
Connor Salerno
Cori Dowden
Cristy Smith
Curtiss Miller
Cynthia Pineda Ramos
Dan Couch
Dane Johannessen
Dania Aboushaban
Daniel Genovese
Daniel Laidler
Daniel Smith
Danielle Ward
Danilo Ching
Daryl Creamer
David Frye
David Irwin
David Morse-Gagne
Dennis Key
Diana Stonehouse
Diana Tavenner
Dorothy Rutherford
Draco Lincoln
Drayke Mash
Dreyfus Tuazon
Duncan Palmer
Dung Luu
Dwight Roberts
Dylan Kressley
Dylan Nichols
Ebony Lincoln
Ed Dunlap
Edward Crown
Edward Doan
Edward Macy
Eleanore Akwe

Elisa Ayala
Elizabeth Feliu
Elizabeth Forsythe
Elizabeth Ross
Emily Hubbard
Emily Macmillan
Emily McCurley
Emily Rossie
Emily Russo
Eric Cecco
ERIC RODRIGUEZ
Eric Schruefer
Erica Marron
Erin Musau
Ethan Watts
Evan Jenkins
Evelyn McEnaney
Fabien Charles
Fatoumata Balde
Francoise Makon
Frank Thomas
Gail Scott
Gregory Day
Guy Hughes
Hadley Sis
Hena Afshari
Hope Ferdinando
Humjot Chahal
Ian Rodriguez
Jacob Birkholz
Jacob Miller
Jahsee Sele
James Armstrong
James Gilmore
James Miser
James Polk
James Spinella-Mamo
James Walsh Jr
Jamie Griffith
Jared Purvis
Jasmine Cerpas
Jason Dawson
Jason Gantick
Jason Hill
Jaudat Ashraf
Javier Orellana Leon
Jay Ramirez-Ayala
Jeffrey Dobies
Jenee Smith
Jennie Terrell
Jennifer Moore
Jennifer Rogers
Jenny Brusehaber
Jeny Clark
Jeremiah Staubs
Jeremy Beavin

Jesse Glendon
Jessi Crawford
Jessica Baadh
Jessica Ferrell
Jessica Sanchez
Jesus Gongora Rocha
Jim Ham
Joe Tatusko
Joe Walsh
Joel Beavin
John Campe
John Evans
John Kish
John Milley
John Oakley
John Sun
Johnathan Ramirez
Jordan McTeague
Joseph Malatak
Josh Rubin
Josh Tuparan
Joshua Johnson
Julia Peck
Juliet Sengendo
Kaitlin McClymont
Kara Miyasato
Karen Kinyua
Kate Reeves
Kate Richards
Katharina Kuron
Katherine Ray
Katherine Singh
Katie Smith
Keith Fava
Kelly Bell
Kelly Dye
Kelvin Lincoln
Kevin Stewart
Kevin Vergara
Khalia Bell
Kim Shebest
Kim Winkler
Kimberley Morris
Larry Dennis
Larry McClintock
Latavia Smith
LaTonya Evans,
Laura Alders
Lauren Dawson
Lauren Pinkney
Lauren Wilch
Laurie Ogden
Lee Lowder
Lense Negara
Liam Barnes
Lindsay Daniels

Loutie Zerbo
Madeline Myers
Madison Eudy
Malcolm Hamilton
Manish Kakadiya
Marc Shea
Marcus Rutherford
Mark Moroz
Martin Ayers
Mary Hamburger
Mary Sullivan
Matthew Ashman
Matthew Berry
Matthew Cherry
Matthew Forrest
Matthew Leach
Matthew Persinger
Matthew Remick
Max Agbayani
Mclain Sullivan
Meeta Bhatnagar
Megan Carnes
Megan Rodriguez
Megan Sochanski
Melissa Lahman
Melissa Lewis
Melodie Callahan
Michael Chang
Michael Gaintner
Michael Greco
Michelle Dulik
Michelle Fradera
Mishu Barua
Mitchell Levendusky
Morgan Cole
Najatee Mcneil
Natalie Greenlee
Natalie Rivera
Nathan Bretscher
Nathaniel Mendoza
Neil Campe
Nicholas Padovani
Nick Buras
Nick Byrne
Nick Frederick
Nick Perez
Nicole Foti
Nicole Vergason
Nimisha Pant
Omid Abbarin
Onika Edwards
Paige Fangmeier
Pamela Brenes
Patricia Alvarenga
Pauline Apisitpaisarn
Pauline Hutton

Preston Lofgran
Quinn Clark
Rachel Mehus
Ray Tsang
Rebecca Brooks
Reese Cooper
Renee Wallace
Richard Madlin
Richard Pellegrino
Robbie Robinson
Robert Ruel
Ronald Eng
Ross Barker
Ryan Blackburn
Ryan Corley
Ryan Dawson
Samiyah Lincoln
Samuel Painter
Sandra Suryanto
Sandy Walker
Sarah Darnell
Sarah Marcello
Sawyer Collins
Scott Carpenter
Scott Koysh
Scott Strong
Sedale Evans
Shadane Williams
Shannon Cool
Sharon Dana
Shawn Nash
Shianna Fenner
Shubham Bahuguna
Slavka Nethercott
Stephanie Mendez Ramirez
Steven Murphy
Susan Lander
Takeisha Farmer
Taliyah Owens
Tanzeela Ahmad
Teresa Lincoln
Terry Connor
Theo Choi
Thomas Arsenault
Thomas Estrada
Thomas Livoti
Tiffany Joyner
Tim Holtz
Timmon Ark
Timothy D Fraser
Tom Galen
Tony Alvarenga
Travis Sines
Trevor Melton
Tyler Clarkson
Tyler Matthews

Tyler McCullough
Wannie Sele
William Ferrara
William Sele
William Sele JR
Windell Wallace
Yazbeth Cruz Espinoza

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

OR

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

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Fernо-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

Dollar amounts in millions except per share amounts or as otherwise specified.

4E

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

Section 1: General Information

Facility Name: Linde Inc.

Physical Address: 32400 North 51st Ave

City: Phoenix State: AZ Zip: 85083

Mailing Address (if different from physical address): 175 East Park Dr Buidling 60

City: Tonawanda State: NY Zip: 14150

Telephone: 716-879-2665 Website: linde.com

Name of Designated Representative (DR): Kellina Anderson

Licensing Company Email: LG.US.BOP.Compliance@linde.com DR Email: kellina.anderson@linde.com

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

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

Name: Linde Gas & Equipment
Address: 601 W Sunset Rd City: Henderson State: NV Zip: 89011

Name: Linde Gas & Equipment
Address: 1290 Glendale Ave City: Sparks State: NV Zip: 89431

Name: University Medical Cente
Address: 800 Rose St City: Las Vegas State: NV Zip: 89106

Name: PAM Specialty Hospital of Las Vegas
Address: 2500 N Tenaya City: Las Vegas State: NV Zip: 89102

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Zamalight Holdco LLC/ Linde PLC
Corporation Name: Linde Inc.
Mailing Address: 10 Riverview Dr
City: Danbury State: CT Zip: 06810
Telephone: 210-837-2000 Email: LG.US.BOP.Compliance@Linde.com
Contact Person Name: Lauren McGowan

Date of SEC Registration: 08/14/2017 | SEC Registration Number: 602527 | Stock Exchange Symbol: LIN

Section 5: Non-Publicly Traded Corporation or Company

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

Section 6: Partnership

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

Section 7: Sole Owner

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

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

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

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

Linde Inc

Facility Name

Margaret Marren

Print Name of Authorized Person Submitting Application

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

05/06/2024

Date

Board Use Only	Date Received: 5/9/24	Amount: $1000.00

Drug Establishments Current Registration Site Linde Inc | FDA

Firm Name	FDA Establishme	DUNS	Business Operations	Address	Registration Ex
Linde Inc.	N/A	119011469	MANUFACTURE	32400 North 51ST Ave, Phoenix, Arizona (AZ) 85086, United States (USA)	12/31/2024

√ verified
MH 5/15/24

0208

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Listed below are the top 4 share holders of Linde PLC and their percentage of ownership:

Top 10 Owners of Linde PLC

Stockholder	Stake	Shares owned	Total value ($)	Shares bought / sold	Total change
The Vanguard Group, Inc.	8.60%	41,952,895	16,237,446,461	-170,689	-0.41%
BlackRock Fund Advisors	4.48%	21,881,137	8,468,875,264	+448,887	+2.09%
SSgA Funds Management, Inc	4.12%	20,118,835	7,786,794,285	+134,593	+0.67%
Massachusetts Financial Services ...	2.48%	12,121,647	4,691,552,255	+231,107	+1.94%

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Linde Inc
USIG Officer Listing

Sean Durbin
Executive Vice President, North America
1585 Sawdust Road, Suite 300, The Woodlands, TX 77380
[redacted]
% Ownership: 0

Hezal Patel
Executive Director Controllership & FP&A
1585 Sawdust Road, Suite 300, The Woodlands, TX 77380
[redacted]
% Ownership: 0

Marcos Cuevas
Vice President, West Region
1620 W Fountainhead Pkwy, Tempe AZ 85282
[redacted]
% Ownership: 0

Wayne DeVantier
Executive Director Compliance & Logistics
[redacted] Tonawanda, NY 14150
[redacted]
% Ownership: 0

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Linde Plc
Officer Listing

Sanjiv Lamba
Chief Executive Officer
[redacted] Danbury CT 06810
% Ownership: 0

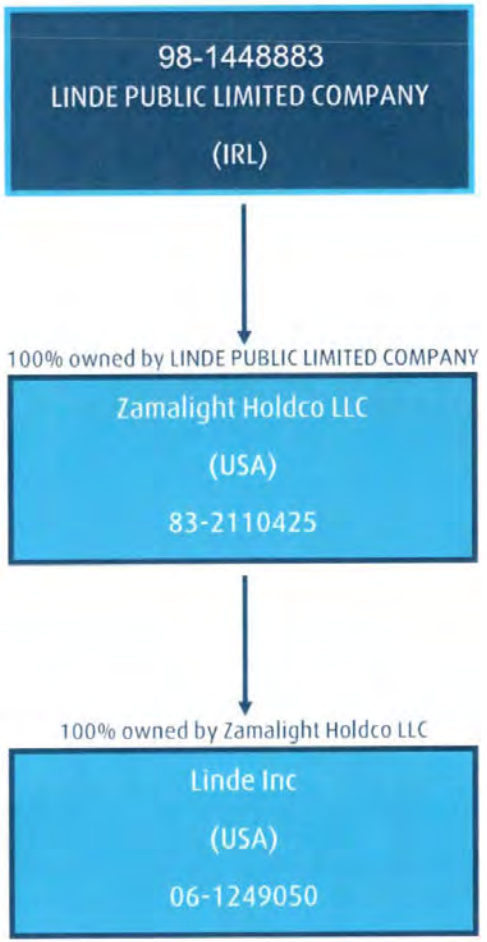
Matthew White
Executive Vice President & Chief Financial Officer
[redacted] Danbury CT 06810
% Ownership: 0

Sean Durbin
Executive Vice President, North America
[redacted] The Woodlands, TX 77380
% Ownership: 0

Juergen Nowicki
Executive Vice president & CEO Linde Engineering
Pullach, Germany
% Ownership: 0

Guillermo Bichara
Executive Vice President & Chief Legal Officer
[redacted] Danbury CT 06810
% Ownership: 0

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Business Name: Linde Inc.
FEIN:06-1249050

Parent Company: Zamalight Holdco Llc
Grandparent Company: Linde Plc

Linde Inc. became an indirect wholly owned subsidiary of Linde plc, and a wholly owned subsidiary of Zamalight Holdco LLC, through the merger with Zamalight Subco. Zamalight Holdco Llc is Linde Inc's Parent Company and Lince Plc is Linde Inc's Grandparent company.

Please see the supporting documentation regarding the ownership change and Linde Inc.'s officers.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LINDE INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF FEBRUARY, A.D. 2024.

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "LINDE INC." WAS INCORPORATED ON THE TWENTY-SIXTH DAY OF OCTOBER, A.D. 1988.

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



Jeffrey W. Bullock, Secretary of State

2176449 8300

SR# 20240476400

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

Authentication: 202797651

Date: 02-13-24

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

Receipt Date: 11/30/2023
Receipt Number: 2023169824
Receipt Amount $: 200.00

Medical Gas - Distributor

PERMIT NO
C002397

EXPIRES
10/31/2025

Issued to :

Linde Inc
John A Sheehy
175 EAST PARK DRIVE BUILDING 60
TONAWANDA, NY 14150

Linde Inc
32400 NORTH 51ST AVE
PHOENIX, AZ 85086

Kam Gandhi
EXECUTIVE DIRECTOR

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

WALLET CARD

NAME : John A Sheehy
LICENSE NUMBER : C002397
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

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

Important Information

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

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

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

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

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED ARE TRUE AND CORRECT COPIES OF ALL DOCUMENTS FILED FROM AND INCLUDING THE RESTATED CERTIFICATE OR A MERGER WITH A RESTATED CERTIFICATE ATTACHED OF "LINDE INC." AS RECEIVED AND FILED IN THIS OFFICE.

THE FOLLOWING DOCUMENTS HAVE BEEN CERTIFIED:

CERTIFICATE OF MERGER, FILED THE THIRTY-FIRST DAY OF OCTOBER, A.D. 2018, AT 8 O`CLOCK A.M.

CERTIFICATE OF OWNERSHIP, FILED THE FIRST DAY OF JUNE, A.D. 2020, AT 4:08 O`CLOCK P.M.

CERTIFICATE OF AMENDMENT, CHANGING ITS NAME FROM "PRAXAIR, INC." TO "LINDE INC.", FILED THE FIRST DAY OF SEPTEMBER, A.D. 2020, AT 11:16 O`CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

2176449 8100X
SR# 20233860608

Authentication: 204489946
Date: 10-31-23

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

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September 25, 2023

To Whom It May Concern,

Linde does not work with control substances; they do not have a DEA certificate. We only deal with medical gases.

Thank you

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/20/2023

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

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

PRODUCER
MARSH USA, LLC.
1166 Avenue of the Americas
New York, NY 10036
Attn: NewYork.Certs@marsh.com Fax: 212-948-0500

CONTACT NAME: Ann-Marie Fleming
PHONE (A/C, No, Ext): 212 345 7960 **FAX (A/C, No):** 212 948 0264
E-MAIL ADDRESS: Ann-Marie.Fleming@marsh.com

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

INSURED
Linde Inc.
10 Riverview Drive
Danbury, CT 06810

COVERAGES **CERTIFICATE NUMBER:** NYC-010962292-20 **REVISION NUMBER:** 28

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			MWZY-313507-23	10/01/2023	10/01/2024	EACH OCCURRENCE	$	5,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	5,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	5,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	5,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY			MWTB-313505-23	10/01/2023	10/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$	10,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	
	DED RETENTION $							$	
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			MWC-313504-23	10/01/2023	10/01/2024	X PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N / A (Mandatory in NH)						E.L. EACH ACCIDENT	$	5,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	5,000,000
							E.L. DISEASE - POLICY LIMIT	$	5,000,000

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

CERTIFICATE HOLDER
Linde Inc.
10 Riverview Drive
Danbury, CT 06810

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

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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The ACORD name and logo are registered marks of ACORD

• Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Linde Inc MDEG License # (if applicable): _____

Physical Address: 32400 North 51st Ave

City: Phoenix State: AZ Zip: 85086

Mailing Address (if different from physical address): 175 East Park Dr Buidling 60

City: Tonawanda State: NY Zip: 14150

Telephone: 7168792665 Website: linde.com

Licensing Company Email: LG.US.BOP.Compliance@linde.com

Section 2: Personal Information

First: Kellina Middle: Maren Last: Anderson

Alias(es, nicknames, name changes, etc.): Kelli Anderson, Kelli M Anderson

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

Mailing Address: [redacted] N North Valley PKwy #2129

City: Phoenix State: AZ Zip: 85085

Telephone: [redacted] Email: Kellina.anderson@linde.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina - Wilmington		07/20 - 07/22	
Address	City	State	Zip
601 College Rd	Wilmington	NC	28403
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Case Western Reserve University		08/06 - 05/10	
Address	City	State	Zip
10900 Euclid Ave	Cleveland	OH	44106
Diploma/Degree obtained, if any			
Bachelors - Chemical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Herbert Henry Dow High School		08/03 - 06/06	
Address	City	State	Zip
3901 N Saginaw Rd	Midland	MI	48640
Diploma/Degree obtained, if any			
High school diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/24 - ~~Present~~ 04/24	[redacted] N North Valley Pkwy	Phoenix	AZ	85085
09/21 - 04/24	[redacted] Poplar Pike	Germantown	TN	38138
07/21 - 09/21	[redacted] Hunters Trl Apt 101	Memphis	TN	38120
08/17 - 07/21	[redacted] E Hill St Unit 102	Signal Hill	CA	90755
08/16 - 08/17	[redacted] Wurlitzer Dr	North Tonawanda	NY	14120
08/14 - 08/16	[redacted] Phillips Rd	Schererville	IN	46375
04/14 - 08/14	[redacted] Aster Dr Apt 1B	Merrillville	IN	46410
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Linde Inc.			05/24-Present	
Business Address		**City**	**State**	**Zip**
32400 N 51st Ave		Phoenix	AZ	85083
Phone	**Title**		**Number of Employed Hours**	
989-859-6966	Director, Operations		420	
Description of Duties				
Manages the Phoenix AZ facility that manufactures and distributes Medical Gases such as NF nitrogen and USP oxygen.				

Business Name			From - To (MM/YY – MM/YY)	
Linde Inc.			06/21-04/24	
Business Address		**City**	**State**	**Zip**
5055 Old Millington Rd		Memphis	TN	38127
Phone	**Title**		**Number of Employed Hours**	
901-354-2023	Facility Manager		6,000	
Description of Duties				
Managed Linde Inc.'s facility in TN that produces medical gases. Administrative licensing for facilities distribution in adjacent states.				

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

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

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

Continue on next page if additional space is needed.

Kellie Adams
6.20.2024

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

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

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

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

Provide explanation below:

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

I, Kellina Anderson, **certify that as the MDEG Administrator for**

Linde Inc.,

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

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

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

Kellina Anderson
Print Name (First, Last)

Kellina Anderson
Original Signature (electronic, copies or stamps not accepted)

04.29.2024
Date

Board Use Only	Date Received: 5/9/24

Linde Inc. List of Employees:
32400 N 51st Ave
Phoenix, AZ 85083

Last Name	First Name	Position Description
Asbell	Michael	Production Technician
Fournier	Patrick	I&E Technician
Pockers	Stephen	I&E Technician
Barbay	Gerald	Production Technician
Cangelosi	Martino	Mechanical Technician
Thomas Miles	Kendron	Production Technician
Doyle	Mark	Production Technician
Zilich	Daniel	Production Technician
Tabaha	Tierney	I&E Technician
Debono	Adam	Production Technician
Veldhuis	Toby	I&E Technician
Greaber	Michael	I&E Technician
Kimp	Darryl	Production Technician
Restrepo	Gonzalo	Dir Ops West Region
Cuevas	Marcos	VP West Region
Anderson	Kellina	Dir Ops

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

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

DATE OF REPORT (Date of earliest event reported): July 24, 2023

Linde plc

(Exact name of registrant as specified in its charter)

Ireland	001-38730	98-1448883
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

10 Riverview Dr. Danbury, Connecticut United States 06810	Forge 43 Church Street West Woking, Surrey GU21 6HT United Kingdom

(Address of principal executive offices) (Zip Code)

+44 1483 242200
(Registrant's telephone numbers, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Ordinary shares (€0.001 nominal value per share)	LIN	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 3.03 Material Modification to Rights of Security Holders.

The rights of shareholders of Linde plc are governed by its Memorandum and Articles of Association (the "Constitution") and the Irish Companies Act 2014. The Constitution was amended at the Annual General Meeting of Shareholders of Linde plc that was held on July 24, 2023 (the "AGM") to reduce certain supermajority shareholder vote requirements (see "Proposal 4" in Item 5.07 below). A copy of the Constitution as amended and restated is filed as Exhibit 3.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 3.03. A description of the amendments to the Constitution is set forth in Linde plc's Definitive Proxy Statement filed with the SEC on May 1, 2023, under the section titled "Proposal 4: Amendments to Linde's Memorandum and Articles of Association to Reduce Certain Supermajority Shareholder Voting Requirements" and is incorporated by reference into this Item 3.03.

ITEM 5.07 Submission of Matters to a Vote of Security Holders

The Linde plc AGM was held on July 24, 2023, at which shareholders voted upon the items set forth below. The total number of shares that were present or represented by proxy at the Annual Meeting was 411,082,505 which was 83.95% of the shares outstanding and entitled to vote and which constituted a quorum. The final voting results of the items submitted to a vote of the shareholders are set forth below.

Proposal 1

The ten nominees for election as a director were elected to serve until the 2024 annual general meeting of shareholders and until his or her successor is elected and qualified. The vote results were as follows:

Director Nominees	Shares For	Shares Against	Shares Abstained	Broker Non-Votes	% of Votes Cast For
Stephen F. Angel	379,268,002	12,302,153	793,853	18,718,497	96.86%
Sanjiv Lamba	386,564,810	4,948,190	851,008	18,718,497	98.74%
Prof DDr. Ann-Kristin Achleitner	370,461,615	21,092,452	809,941	18,718,497	94.61%
Dr. Thomas Enders	385,655,871	6,020,848	687,289	18,718,497	98.46%
Hugh Grant	379,888,078	11,781,450	694,480	18,718,497	96.99%
Joe Kaeser	300,400,717	84,238,259	7,725,032	18,718,497	78.10%
Victoria E. Ossadnik	373,173,756	18,512,444	677,808	18,718,497	95.27%
Prof. Dr. Martin H. Richenhagen	371,753,286	19,883,901	726,821	18,718,497	94.92%
Alberto Weisser	385,777,566	5,882,787	703,655	18,718,497	98.50%
Robert L. Wood	384,279,497	7,366,642	717,869	18,718,497	98.12%

Proposal 2a

Shareholders ratified, on an advisory and non-binding basis, the appointment of PricewaterhouseCoopers ("PWC") as the independent auditor by the votes set forth below.

Shares Voted For	Shares Voted Against	Shares Abstained	Broker Non-Votes
390,337,540	20,505,674	239,291	N/A
(94.95% of votes cast)	(4.98% of votes cast)		

Proposal 2b

Shareholders approved the authorization of the Board, acting through the Audit Committee, to determine PWC's remuneration by the votes set forth below.

Shares Voted For	Shares Voted Against	Shares Abstained	Broker Non-Votes
403,800,710	6,888,594	393,201	N/A
(98.23% of votes cast)	(1.68% of votes cast)		

Proposal 3

Shareholders approved, on an advisory and non-binding basis, the compensation of Linde plc's Named Executive Officers as disclosed in the 2023 proxy statement by the votes set forth below.

Shares Voted For	Shares Voted Against	Shares Abstained	Broker Non-Votes
374,237,043	17,505,109	621,856	18,718,497
(95.38% of votes cast)	(4.46% of votes cast)		

Proposal 4

Shareholders approved the proposal to amend Linde's Irish Memorandum and Articles of Association to reduce certain supermajority shareholder vote requirements.

Shares Voted For	Shares Voted Against	Shares Abstained	Broker Non-Votes
390,900,058	1,123,465	340,485	18,718,497
(99.63% of votes cast)	(0.29% of votes cast)		

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits. The following exhibit is furnished herewith pursuant to Item 3.03 hereof:

Exhibit No.	Description
3.1	Amended and Restated Memorandum and Articles of Association of Linde plc dated July 24, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LINDE PLC

By: /s/ Guillermo Bichara
Name: Guillermo Bichara
Title: Chief Legal Officer

Date: July 28, 2023

Companies Act 2014

PUBLIC LIMITED COMPANY

CONSTITUTION

OF

LINDE PUBLIC LIMITED COMPANY

MEMORANDUM OF ASSOCIATION

1. The name of the Company is LINDE PUBLIC LIMITED COMPANY.

2. The Company is a public limited company, registered under Part 17 of the Companies Act 2014.

3. The objects for which the Company is established are:

   3.1 To carry on the business of a holding company and to co-ordinate the administration, finances and activities of any subsidiary companies or associated companies, to do all lawful acts and things whatever that are necessary or convenient in carrying on the business of such a holding company and in particular to carry on in all its branches the business of a management services company, to act as managers and to direct or coordinate the management of other companies or of the business, property and estates of any company or person and to undertake and carry out all such services in connection therewith as may be deemed expedient by the Company's board of directors and to exercise its powers as a shareholder of other companies.

   3.2 To carry on the businesses of manufacturer, distributor, wholesaler, retailer, service provider, investor, designer, trader and any other business (except the issuing of policies of insurance) which may seem to the Company's board of directors capable of being conveniently carried on in connection with these objects or calculated directly or indirectly to enhance the value of or render more profitable any of the Company's property.

   3.3 To carry on all or any of the businesses as aforesaid either as a separate business or as the principal business of the Company.

   3.4 To invest and deal with the property of the Company in such manner as may from time to time be determined by the Company's board of directors and to dispose of or vary such investments and dealings.

   3.5 To borrow or raise money or capital in any manner and on such terms and subject to such conditions and for such purposes as the Company's board of directors shall think fit or expedient, whether alone or jointly and/or severally with any other person or company, including, without prejudice to the generality of the foregoing, whether by the issue of debentures or debenture stock (perpetual or otherwise) or otherwise, and to secure, with or without consideration, the payment or repayment of any money borrowed, raised or owing or any debt, obligation or liability of the Company or of any other person or company whatsoever in such manner and on such terms and conditions as the Company's board of directors shall think fit or expedient and, in particular by mortgage, charge, lien, pledge or debenture or any other security of whatsoever nature or howsoever described, perpetual or otherwise, charged upon all or any of the Company's property, both present and future, and to purchase, redeem or pay off any such securities or borrowings and also to accept capital contributions from any person or company in any manner and on such terms and conditions and for such purposes as the Company's board of directors shall think fit or expedient.

3.6 To lend and advance money or other property or give credit or financial accommodation to any company or person in any manner either with or without security and whether with or without the payment of interest and upon such terms and conditions as the Company's board of directors shall think fit or expedient.

3.7 To guarantee, indemnify, grant indemnities in respect of, enter into any suretyship or joint obligation, or otherwise support or secure, whether by personal covenant, indemnity or undertaking or by mortgaging, charging, pledging or granting a lien or other security over all or any part of the Company's property (both present and future) or by any one or more of such methods or any other method and whether in support of such guarantee or indemnity or suretyship or joint obligation or otherwise, on such terms and conditions as the Company's board of directors shall think fit, the payment of any debts or the performance or discharge of any contract, obligation or liability of any person or company (including, without prejudice to the generality of the foregoing, the payment of any capital, principal, dividends or interest on any stocks, shares, debentures, debenture stock, notes, bonds or other securities of any person, authority or company) including, without prejudice to the generality of the foregoing, any company which is for the time being the Company's holding company or another subsidiary (as defined by the Act) of the Company's holding company or a subsidiary of the Company or otherwise associated with the Company (including any arrangements of the Company or any of its subsidiaries described in paragraph 3.19), in each case notwithstanding the fact that the Company may not receive any consideration, advantage or benefit, direct or indirect, from entering into any such guarantee or indemnity or suretyship or joint obligation or other arrangement or transaction contemplated herein.

3.8 To grant, convey, assign, transfer, exchange or otherwise alienate or dispose of any property of the Company of whatever nature or tenure for such price, consideration, sum or other return whether equal to or less than the market value thereof or for shares, debentures or securities and whether by way of gift or otherwise as the Company's board of directors shall deem fit or expedient and where the property consists of real property to grant any fee farm grant or lease or to enter into any agreement for letting or hire of any such property for a rent or return equal to or less than the market or rack rent therefor or at no rent and subject to or free from covenants and restrictions as the Company's board of directors shall deem appropriate.

3.9 To purchase, take on, lease, exchange, rent, hire or otherwise acquire any property and to acquire and undertake the whole or any part of the business and property of any company or person.

3.10 To develop and turn to account any land acquired by the Company or in which it is interested and in particular by laying out and preparing the same for building purposes, constructing, altering, pulling down, decorating, maintaining, fitting out and improving buildings and conveniences and by planting, paving, draining, farming, cultivating, letting and by entering into building leases or building agreements and by advancing money to and entering into contracts and arrangements of all kinds with builders, contractors, architects, surveyors, purchasers, vendors, tenants and any other person.

3.11 To construct, improve, maintain, develop, work, manage, carry out or control any property which may seem calculated directly or indirectly to advance the Company's interest and to contribute to, subsidise or otherwise assist or take part in the construction, improvement, maintenance, working, management, carrying out or control thereof.

3.12 To draw, make, accept, endorse, discount, execute and issue promissory notes, bills of exchange, bills of lading, warrants, debentures and other negotiable or transferable instruments.

3.13 To engage in currency exchange, interest rate and commodity transactions including, but not limited to, dealings in foreign currency, spot and forward rate exchange contracts, futures, options, forward rate agreements, swaps, caps, floors, collars and any other foreign exchange, interest rate or commodity hedging arrangements and such other instruments as are similar to, or derived from, any of the foregoing whether for the purpose of making a profit or avoiding a loss or managing a currency, interest rate or commodity exposure or any other exposure or for any other purpose.

3.14 As a pursuit in itself or otherwise and whether for the purpose of making a profit or avoiding a loss or managing a currency, interest rate or commodity exposure or any other exposure or for any other purpose whatsoever, to engage in any currency exchange transactions, interest rate transactions and commodity transactions, derivative and/or treasury transactions and any other financial or other transactions, including (without prejudice to the generality of the foregoing) securitisation, treasury and/or structured finance transactions, of whatever nature in any manner and on any terms and for any purposes whatsoever, including, without prejudice to the generality of the foregoing, any transaction entered into in connection with or for the purpose of, or capable of being for the purposes of, avoiding, reducing, minimising, hedging against or otherwise managing the risk of any loss, cost, expense, or liability arising, or which may arise, directly or indirectly, from a change or changes in any interest rate or currency exchange rate or in the price or value of any property, asset, commodity, index or liability or from any other risk or factor affecting the Company's business, including but not limited to dealings whether involving purchases, sales or otherwise in foreign currency, spot and/or forward rate exchange contracts, futures, options, forward rate agreements, swaps, caps, floors, collars and/or any such other currency or interest rate or commodity or other hedging, treasury or structured finance arrangements and such other instruments as are similar to, or derived from any of the foregoing.

3.15 To apply for, establish, create, purchase or otherwise acquire, sell or otherwise dispose of and hold any patents, trade marks, copyrights, brevets d'invention, registered designs, licences, concessions and the like conferring any exclusive or non-exclusive or limited rights to use or any secret or other information and any invention and to use, exercise, develop or grant licences in respect of or otherwise turn to account or exploit the property, rights or information so held.

3.16 To enter into any arrangements with any governments or authorities, national, local or otherwise and to obtain from any such government or authority any rights, privileges and concessions and to carry out, exercise and comply with any such arrangements, rights, privileges and concessions.

3.17 To establish, form, register, incorporate or promote any company or companies or person, whether inside or outside of Ireland.

3.18 To procure that the Company be registered or recognised whether as a branch or otherwise in any country or place.

3.19 To enter into partnership or into any arrangement for sharing profits, union of interests, co-operation, joint venture, reciprocal concession or otherwise with any person or company carrying on or engaged in or about to carry on or engage in any business or transaction and to engage in any transaction in connection with the foregoing.

3.20 To acquire or amalgamate with any other company or person.

3.21 To acquire and undertake the whole or any part of the business, good-will and assets of any person, firm or company carrying on or proposing to carry on any of the businesses which this Company is authorised to carry on, and as part of the consideration for such acquisition to undertake all or any of the liabilities of such person, firm or company, or to acquire an interest in, amalgamate with, or enter into any arrangement for sharing profits, or for co-operation, or for mutual assistance with any such person, firm or company and to give or accept by way of consideration for any of the acts or things aforesaid or property acquired, any shares, debentures, debenture stock or securities that may be agreed upon, and to hold and retain or sell, mortgage or deal with any shares, debentures, debenture stock or securities so received.

3.22 To promote freedom of contract, and to resist, insure against, counteract and discourage interference therewith, to join any lawful federation, union or association, or do any other lawful act or thing with a view to preventing or resisting directly or indirectly any interruption of or interference with the Company's or any other trade or business or providing or safeguarding against the same, or resisting or opposing any strike, movement or organisation which may be thought detrimental to the interests of the Company or its employees and to subscribe to any association or fund for any such purposes.

3.23 To make gifts to any person or company including, without prejudice to the generality of the foregoing, capital contributions and to grant bonuses to the directors or any other persons or companies who are or have been in the employment of the Company including substitute directors and any other officer or employee.

3.24 To establish and support or aid in the establishment and support of associations, institutions, funds, trusts and conveniences calculated to benefit directors, ex-directors, employees or ex-employees of the Company or any subsidiary of the Company or the dependants or connections of such persons, and to grant pensions and allowances upon such terms and in such manner as the Company's board of directors think fit, and to make payments towards insurance and to subscribe or guarantee money for charitable or benevolent objects or for any exhibition or for any public, general or useful object, or any other object whatsoever which the Company's board of directors may think advisable.

3.25 To establish and contribute to any scheme for the purchase of shares or subscription for shares in the Company, its holding company or any of its or their respective subsidiaries, to be held for the benefit of the employees or former employees of the Company or any subsidiary of the Company including any person who is or was a director holding a salaried employment or office in the Company or any subsidiary of the Company and to lend or otherwise provide money to the trustees of such schemes or the employees or former employees of the Company or any subsidiary of the Company to enable them to purchase shares of the Company, its holding company or any of its or their respective subsidiaries and to formulate and carry into effect any scheme for sharing the profits of the Company, its holding company or any of its or their respective subsidiaries with its employees and/or the employees of any of its subsidiaries.

3.26 To remunerate any person or company for services rendered or to be rendered in placing or assisting to place or guaranteeing the placing of any of the shares of the Company's capital or any debentures, debenture stock or other securities of the Company or in or about the formation or promotion of the Company or the conduct of its business.

3.27 To obtain any Act of the Oireachtas or provisional order for enabling the Company to carry any of its objects into effect or for effecting any modification of the Company's constitution or for any other purpose which may seem expedient and to oppose any proceedings or applications which may seem calculated directly or indirectly to prejudice the Company's interests.

3.28 To adopt such means of making known the products of the Company as may seem expedient and in particular by advertising in the press, by circulars, by purchase and exhibition of works of art or interest, by publication of books and periodicals and by granting prizes, rewards and donations.

3.29 To undertake and execute the office of trustee and nominee for the purpose of holding and dealing with any property of any kind for or on behalf of any person or company; to act as trustee, nominee, agent, executor, administrator, registrar, secretary, committee or attorney generally for any purpose and either solely or with others for any person or company; to vest any property in any person or company with or without any declared trust in favour of the Company.

3.30 To pay all costs, charges, fees and expenses incurred or sustained in or about the promotion, establishment, formation and registration of the Company.

3.31 To do all or any of the above things in any part of the world, and as principals, agents, contractors, trustees or otherwise and by or through trustees, agents or otherwise and either alone or in conjunction with any person or company.

3.32 To distribute the property of the Company in specie among the members or, if there is only one, to the sole member of the Company.

3.33 To do all such other things as the Company's board of directors may think incidental or conducive to the attainment of the above objects or any of them.

NOTE: it is hereby declared that in this memorandum of association:

a) the word "company", except where used in reference to this Company, shall be deemed to include a body corporate, whether a company (wherever formed, registered or incorporated), a corporation aggregate, a corporation sole and a national or local government or other legal entity; and

b) the word "person", shall be deemed to include any individual, firm, body corporate, association or partnership, government or state or agency of a state, local authority or government body or any joint venture association or partnership (whether or not having a separate legal personality) and that person's personal representatives, successors or permitted assigns; and

c) the word "property", shall be deemed to include, where the context permits, real property, personal property including choses or things in action and all other intangible property and money and all estates, rights, titles and interests therein and includes the Company's uncalled capital and future calls and all and every other undertaking and asset; and

d) a word or expression used in this memorandum of association which is not otherwise defined and which is also used in the Companies Act 2014, as amended, shall have the same meaning here, as it has in the Companies Act 2014, as amended; and

e) any phrase introduced by the terms "including", "include" and "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms, whether or not followed by the phrases "but not limited to", "without prejudice to the generality of the foregoing" or any similar expression; and

f) words denoting the singular number only shall include the plural number and vice versa and references to one gender includes all genders; and

g) it is intended that the objects specified in each paragraph in this clause shall, except where otherwise expressed in such paragraph, be separate and distinct objects of the Company and shall not be in any way limited or restricted by reference to or inference from the terms of any other paragraph or the order in which the paragraphs of this clause occur or the name of the Company.

4. The liability of the members is limited.

5. The authorised share capital of the Company is €1,825,000 divided into 1,750,000,000 ordinary shares of €0.001 each, 25,000 A ordinary shares of €1.00 each, 25,000 deferred shares of €1.00 each and 25,000,000 preferred shares of €0.001 each.

6. The shares forming the capital, may be increased or reduced and be divided into such classes and issued with any special rights, privileges and conditions or with such qualifications as regards preference, dividend, capital, voting or other special incidents, and be held upon such terms as may be attached thereto or as may from time to time be provided by the original or any substituted or amended articles of association and regulations of the Company for the time being, but so that where shares are issued with any preferential or special rights attached thereto such rights shall not be alterable otherwise than pursuant to the provisions of the Company's articles of association for the time being.

LINDE PUBLIC LIMITED COMPANY

ARTICLES OF ASSOCIATION

Interpretation and general

1. Sections 83, 84 and, for the avoidance of doubt, 117(9) of the Act shall apply to the Company but, subject to that, the provisions set out in these Articles shall constitute the whole of the regulations applicable to the Company and no other "optional provisions" as defined by section 1007(2) of the Act shall apply to the Company.

2. In these Articles:

2.1 "**Act**", means the Companies Act 2014 and every statutory modification and re-enactment thereof for the time being in force;

2.2 "**Adoption Date**", means the effective date of adoption of these Articles;

2.3 "**Approved Nominee**", means a person appointed under contractual arrangements with the Company to hold shares or rights or interests in shares of the Company on a nominee basis;

2.4 "**Article**", means an article of these Articles;

2.5 "**Articles**", means these articles of association as from time to time and for the time being in force;

2.6 "**Auditors**", means the auditors for the time being of the Company;

2.7 "**A Ordinary Shares**", means the A ordinary shares of €1.00 each in the capital of the Company;

2.8 "**Board**", means the board of Directors of the Company;

2.9 "**Chairman**", means the person occupying the position of Chairman of the Board from time to time;

2.10 "**Chief Executive Officer**", shall include any equivalent office;

2.11 "**Clear Days**", means, in relation to a period of notice, that period excluding the day when the notice is given or deemed to be given and excluding the day for which notice is being given or on which an action or event for which notice is being given is to occur or take effect;

2.12 "**Company**", means the company whose name appears in the heading to these Articles;

2.13 "**Company Secretary**", means the person or persons appointed as company secretary or joint company secretary of the Company from time to time and shall include any assistant or deputy secretary;

2.14 "**Deferred Shares**", means the deferred shares of €1.00 each in the capital of the Company;

2.15 "**Directors**", means the directors for the time being of the Company or any of them acting as the Board;

2.16 **"electronic communication"**, has the meaning given to that word in the Electronic Commerce Act 2000 and in addition includes in the case of notices or documents issued on behalf of the Company, such documents being made available or displayed on a website of the Company (or a website designated by the Board);

2.17 **"Exchange"**, means any securities exchange or other system on which the shares of the Company may be listed or otherwise authorised for trading from time to time in circumstances where the Company has approved such listing or trading;

2.18 **"Exchange Act"**, means the Securities Exchange Act of 1934 of the United States, as amended;

2.19 **"Group"**, means the Company and its subsidiaries from time to time and for the time being;

2.20 **"member"**, means in relation to any share, the member whose name is entered in the Register as the holder of the share or, where the context permits, the members whose names are entered in the Register as the joint holders of shares and shall include a member's personal representatives in consequence of his or her death or bankruptcy;

2.21 **"Memorandum"**, means the memorandum of association of the Company;

2.22 **"Office"**, means the registered office for the time being of the Company;

2.23 **"Ordinary Shares"**, means the ordinary shares of €0.001 each in the capital of the Company;

2.24 **"Preferred Shares"**, means the preferred shares of €0.001 each in the capital of the Company;

2.25 **"Redeemable Shares"**, means redeemable shares as defined by section 64 of the Act;

2.26 **"Register"**, means the register of members of the Company to be kept as required by the Act;

2.27 **"Scheme"**, means the scheme of arrangement published by Rounderway Public Limited Company (previously known as "Linde Public Limited Company" and incorporated in Ireland with company number 602527) on 9 December 2022;

2.28 **"SEC"**, means the U.S. Securities and Exchange Commission.

NOTE: it is hereby declared that in these Articles:

a) the word "company", except where used in reference to this Company, shall be deemed to include a body corporate, whether a company (wherever formed, registered or incorporated), a corporation aggregate, a corporation sole and a national or local government or other legal entity; and

b) the word "person", shall be deemed to include any individual, firm, body corporate, association or partnership, government or state or agency of a state, local authority or government body or any joint venture association or partnership (whether or not having a separate legal personality) and that person's personal representatives, successors or permitted assigns; and

c) the word "property", shall be deemed to include, where the context permits, real property, personal property including choses or things in action and all other intangible property and money and all estates, rights, titles and interests therein and includes the Company's uncalled capital and future calls and all and every other undertaking and asset; and

d) a word or expression used in the Articles which is not otherwise defined and which is also used in the Act shall have the same meaning here, as it has in the Act; and

e) any phrase introduced by the terms "including", "include" and "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms, whether or not followed by the phrases "but not limited to", "without prejudice to the generality of the foregoing" or any similar expression; and

f) words denoting the singular number only shall include the plural number and vice versa and references to one gender includes all genders.

Authorised share capital

3. The authorised share capital of the Company is €1,825,000 divided into 1,750,000,000 Ordinary Shares of €0.001 each, 25,000 A Ordinary Shares of €1.00 each, 25,000 Deferred Shares of €1.00 each and 25,000,000 preferred shares of €0.001 each.

Rights attaching to Ordinary Shares and A Ordinary Shares

4. The Ordinary Shares and the A Ordinary Shares shall entitle the holders thereof to the following rights:

4.1 subject to the right of the Company to set record dates for the purposes of determining the identity of members entitled to notice of and/or to vote at a general meeting and the authority of the Board and chairperson of the meeting to maintain order and security, the right to attend any general meeting of the Company and to exercise one vote per Ordinary Share and one vote per A Ordinary Share held at any general meeting of the Company;

4.2 the right to participate pro rata in all dividends declared by the Company; and

4.3 the right, in the event of the Company's winding up, to participate pro rata in the total assets of the Company.

5. The rights attaching to the Ordinary Shares may be subject to the terms of issue of any series or class of Preferred Shares allotted by the Directors from time to time in accordance with Article 6.

Rights attaching to Preferred Shares

6. The Board is empowered to cause the Preferred Shares to be issued from time to time as shares of one or more series of Preferred Shares, and in the resolution or resolutions providing for the issue of Preferred Shares of each particular series, before issuance, the Board is expressly authorised to fix:

6.1 the distinctive designation of such series and the number of shares which shall constitute such series, which number may be increased (except as otherwise provided by the Board in creating such series) or decreased (but not below the number of shares thereof then in issue) from time to time by resolution of the Board;

6.2 the rate of dividends payable on shares of such series, if any, whether or not and upon what conditions dividends on shares of such series shall be cumulative and, if cumulative, the date or dates from which dividends shall accumulate and the preference or relation which such dividends shall bear to the dividends payable on any other class or classes or on any other series of share capital;

6.3 the terms, if any, on which shares of such series may be redeemed, including without limitation, the redemption price or prices for such series, which may consist of a redemption price or scale of redemption prices applicable only to redemption in connection with a sinking fund (which term as used herein shall include any fund or requirement for the periodic purchase or redemption of shares), and the same or a different redemption price or scale of redemption prices applicable to any other redemption;

6.4 the terms and amount of any sinking fund provided for the purchase or redemption of shares of such series;

6.5 the amount or amounts which shall be paid to the holders of shares of such series in case of liquidation, dissolution or winding up of the Company, whether voluntary or involuntary;

6.6 the terms, if any, upon which the holders of shares of such series may convert shares thereof into shares of any other class or classes or of any one or more series of the same class or of another class or classes;

6.7 the voting rights, full or limited, if any, of the shares of such series; and whether or not and under what conditions the shares of such series (alone or together with the shares of one or more other series having similar provisions) shall be entitled to vote separately as a single class, for the election of one or more additional Directors in case of dividend arrears or other specified events, or upon other matters;

6.8 whether or not the holders of shares of such series, as such, shall have any pre-emptive or preferential rights to subscribe for or purchase shares of any class or series of shares of the Company, now or hereafter authorised, or any securities convertible into, or warrants or other evidences of optional rights to purchase or subscribe for, shares of any class or series of the Company, now or hereafter authorised;

6.9 the limitations and restrictions, if any, to be effective while any shares of such series are outstanding upon the payment of dividends, or the making of other distributions on, and upon the purchase, redemption or other acquisition by the Company of, any other class or classes of shares ranking junior to the shares of such series either as to dividends or upon liquidation, dissolution or winding up;

6.10 the conditions or restrictions, if any, upon the creation of indebtedness of the Company or upon the issuance of any additional shares (including additional shares of such series or of any other class) ranking on a parity with or prior to the shares of such series as to dividends or distribution of assets upon liquidation; and

6.11 such other rights, preferences and limitations as may be permitted to be fixed by the Board of the Company under the laws of Ireland as in effect at the time of the creation of such series.

7. The Board is authorised to change the designations, rights, preferences and limitations of any series of Preferred Shares theretofore established, no shares of which have been issued.

8. The rights conferred upon the member of any pre-existing shares in the share capital of the Company shall be deemed not to be varied by the creation, issue and allotment of Preferred Shares in accordance with these Articles.

9. Unless the Board determines otherwise, any share in the capital of the Company shall be deemed to be a Redeemable Share on, and from the time of, the existence or creation of an agreement, transaction or trade between the Company and any person (who may or may not be a member) pursuant to which the Company acquires or will acquire a share in the capital of the Company, or an interest in shares in the capital of the Company, from the relevant person, save for an acquisition for nil consideration pursuant to section 102(1)(a) of the Act. In these circumstances, the acquisition of such shares by the Company, save where acquired for nil consideration in accordance with the Act, shall constitute the redemption of a Redeemable Share in accordance with Chapter 6 of Part 3 of the Act. No resolution, whether special or otherwise, shall be required to be passed to deem any share in the capital of the Company a Redeemable Share.

CERTIFICATE OF MERGER

OF

ZAMALIGHT SUBCO, INC.

INTO

PRAXAIR, INC.

October 31, 2018

Pursuant to Title 8, Section 251(c) of the Delaware General Corporation Law (the "DGCL"), the undersigned corporation does hereby certify as follows:

1. The name and state of incorporation of each of the constituent corporations of the merger (collectively, the "Constituent Corporations") are as follows:

Name	State of Incorporation
Zamalight Subco, Inc.	Delaware
Praxair, Inc.	Delaware

2. A Business Combination Agreement, which includes an agreement and plan of merger between the Constituent Corporations (the "Agreement"), dated as of June 1, 2017 has been approved, adopted, certified, executed and acknowledged by each of the Constituent Corporations in accordance with Section 251(c) of the DGCL and, in the case of Zamalight Subco, Inc., Section 228 of the DGCL.

3. The name of the surviving corporation is Praxair, Inc.

4. By virtue of the merger, the Certificate of Incorporation of the surviving corporation will be amended and restated in its entirety to read as set forth in Exhibit A hereto, and as so amended shall be the Amended and Restated Certificate of Incorporation of the surviving corporation until thereafter amended in accordance with applicable law.

5. The executed Agreement is on file at 10 Riverview Drive, Danbury, CT 06810-6268, the place of business of the surviving corporation.

6. A copy of the Agreement will be furnished by the surviving corporation on request and without cost, to any stockholder of the Constituent Corporations.

State of Delaware
Secretary of State
Division of Corporations
Delivered 08:00 AM 10/31/2018
FILED 08:00 AM 10/31/2018
SR 20187405415 - File Number 2176449

7. The merger shall be effective on October 31, 2018 immediately upon the filing of this Certificate of Merger with the Secretary of State of the State of Delaware.

IN WITNESS WHEREOF, the surviving corporation has caused this certificate to be signed by an authorized officer as of the date first written above.

PRAXAIR, INC.

By 

Name: Guillermo Bichara
Title: Authorized Officer

[Signature Page to Certificate of Merger]

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
PRAXAIR, INC.

FIRST. The name of the corporation is Praxair, Inc.

SECOND. The address of the corporation's registered office in the State of Delaware is 251 Little Falls Drive, in the City of Wilmington, County of New Castle, 19808. The name of the registered agent at such address is Corporation Service Company.

THIRD. The purpose of the corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware and to engage in any and all activities necessary or incidental to the foregoing.

FOURTH. The total number of shares which the corporation shall have authority to issue is 1 share of Common Stock, and the par value of such share is $0.01.

FIFTH. Elections of directors need not be by written ballot except and to the extent provided in the by-laws of the corporation.

SIXTH. The number of directors of the corporation shall be fixed from time to time in the manner provided in the by-laws of the corporation. Each director shall be elected and shall hold office until the annual meeting next succeeding his or her election and until his or her successor shall be elected and qualified, subject, however, to prior death, resignation, retirement, disqualification or removal from office. Any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares at the time entitled to vote at an election of directors.

SEVENTH. A director of the corporation shall not be liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent that such exemption from liability or limitation thereof is not permitted under the Delaware General Corporation Law as currently in effect or as the same may hereafter be amended. No amendment, modification or repeal of this Article SEVENTH shall adversely affect any right or protection of a director that exists at the time of such amendment, modification or repeal.

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:08 PM 06/01/2020
FILED 04:08 PM 06/01/2020
SR 20205378399 - File Number 2176449

CERTIFICATE OF OWNERSHIP AND MERGER

OF

LINDE DELAWARE INVESTMENTS INC.
(a Delaware corporation)

with and into

PRAXAIR, INC.
(a Delaware corporation)

(Pursuant to Section 253 of the General
Corporation Law of Delaware)

Pursuant to Section 253 of the Delaware General Corporation Law, the undersigned corporation, organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify:

FIRST. The name of the surviving corporation is the parent, Praxair, Inc. (the "Surviving Corporation"), a Delaware corporation, and the name of the subsidiary corporation being merged into this Surviving Corporation is Linde Delaware Investments Inc., a Delaware corporation ("Non-surviving Corporation").

SECOND. The resolution approving the merger of the Non-surviving Corporation with and into the Surviving Corporation was approved by the Board of Directors of the Surviving Corporation on May 27, 2020, in the form attached to this certificate as Exhibit A.

THIRD. The name of the Surviving Corporation is Praxair, Inc., a Delaware corporation.

FOURTH. The Certificate of Incorporation of the Surviving Corporation shall remain its Certificate of Incorporation.

FIFTH. The merger is to become effective at 11:59 p.m., Eastern Standard Time, on May 31, 2020. For Accounting Purposes Only.

SIXTH. The Agreement of Merger referred to in the resolution set forth on Exhibit A is on file at 10 Riverview Drive, Danbury, Connecticut 06810.

SEVENTH. A copy of the Agreement of Merger will be furnished by the surviving corporation on request, without cost, to any stockholder of the constituent corporations.

EIGHTH. The Surviving Corporation owns 100% of the outstanding capital stock of the Non-surviving Corporation.

IN WITNESS WHEREOF, the Surviving Corporation has caused this certificate to be signed by an authorized officer this 27th day of May 2020.

PRAXAIR, INC.

By: _____
Name: Anthony M. Pepper
Title: Assistant Secretary

Exhibit A

RESOLVED, that (i) approval is hereby given for the merger of Linde Delaware Investments Inc. (the "Non-Surviving Corporation"), a Delaware corporation and a wholly-owned subsidiary of Praxair, Inc., a Delaware corporation (the "Corporation"), with and into the Corporation, with the Corporation being the surviving corporation (the "Surviving Corporation"), in accordance with the terms and conditions of the Agreement of Merger presented at this meeting of the Corporation's Board of Directors, and (ii) the Agreement of Merger is hereby adopted and approved.

FURTHER RESOLVED, that any officer of the Corporation is hereby authorized and directed to do the following on behalf of the Corporation, (i) to execute and deliver the Agreement of Merger, (ii) to have prepared, to execute and to file an appropriate Certificate of Ownership and Merger with the office of the Secretary of State of the State of Delaware, (iii) to terminate and abandon the Agreement of Merger with the Non-Surviving Corporation at any time so long as the Certificate of Ownership and Merger referred to in the Agreement of Merger has not yet been filed with the office of the Secretary of State of the State of Delaware, and (iv) to execute, deliver and/or file all such other documents and take all such other action as may be necessary or appropriate to perform the obligations of this Corporation under and to consummate the Agreement of Merger.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "PRAXAIR, INC.", CHANGING ITS NAME FROM "PRAXAIR, INC." TO "LINDE INC.", FILED IN THIS OFFICE ON THE FIRST DAY OF SEPTEMBER, A.D. 2020, AT 11:16 O`CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

2176449 8100
SR# 20207045580

Authentication: 203574146
Date: 09-01-20

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

LINDE INC.

ASSISTANT SECRETARY'S CERTIFICATE

I, Anthony M. Pepper, Assistant Secretary of LINDE INC., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), DO HEREBY CERTIFY that the following are true and correct resolutions adopted by the Board of Directors of said Corporation in a Unanimous Consent of Directors dated June 24, 1992, and that said resolutions are still in full force and effect:

RESOLVED, that the general enabling resolutions adopted by the Board on November 8, 1988 are amended and restated in their entirety as follows:

"RESOLVED, that the Chairman, the Chief Executive Officer, the President, any Vice-President, the Chief Financial Officer, the Treasurer, the Secretary, any Assistant Treasurer or any Assistant Secretary of the Corporation is authorized, in the name and on behalf of the Corporation, to execute and deliver any contract, agreement or document, to enter into any commitment or obligation, or to take or do or cause to be taken or done any action or thing, for the conduct of the business of the Corporation in the ordinary course thereof; and be it further

RESOLVED, that the Chief Executive Officer or the President of the Corporation is authorized to appoint executives of a business, division or department of the Corporation, to designate their titles, to fix their compensation, and to prescribe their duties; and be it further

RESOLVED, that the President, or any Vice-President of the Corporation responsible for a business, division or department of the Corporation is authorized to appoint other agents and employees for such component, to designate their titles, if any, to fix their compensation, and to prescribe their duties; and be it further

RESOLVED, that any officer or manager referred to above is authorized to designate in writing one or more employees or representative to do any act or thing which said officer or manager is authorized to do pursuant to the foregoing resolutions; and be it further

RESOLVED, that any person dealing with the Corporation may conclusively rely on a certificate from the Secretary or an Assistant Secretary of the Corporation or on an opinion from an attorney employed by or otherwise representing the Corporation that an officer, manager or other person is authorized to act for the Corporation in a particular matter."

AND I DO HEREBY FURTHER CERTIFY that Margaret Marren, Director of Compliance and Andrew Deneka, Manager, Operations Plant Support of the Corporation, be and they each are fully authorized to complete state applications, including any affidavits which may be a part thereof, for pharmacy licenses required pursuant to the Federal Prescription Drug Marketing Act of 1987.

IN WITNESS WHEREOF, I have set my hand this 4th day of April 2022.

Assistant Secretary

Subscribed and sworn to before me
this 4th day of April 2022

Notary Public

MELISSA A. MAZAL
Notary Public, State of Connecticut
My Commission Expires Feb. 28, 2025

4F

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: Mako Surgical Corp.

Physical Address: 3365 Enterprise Ave

City: Weston State: FL Zip: 33331

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

City: _____ State: _____ Zip: _____

Telephone: 954-232-8627 Website: www.stryker.com

Name of Designated Representative (DR): Fernando Santana

Licensing Company Email: statelicensing1@stryker.com DR Email: fernando.santana@stryker.com

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

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

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

FERNANDO SANTANA

Original Signature (electronic, copies or stamps not accepted)

JUNE 05, 2024

Date

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

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Stryker Corporation (SYK)

Corporation Name: Mako Surgical Corp

Mailing Address: 3365 Enterprise Ave

City: Weston State: FL Zip: 33331

Telephone: 269-385-2600 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

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

Mako Surgical Corp

Facility Name

Fernando Santana

Print Name of Authorized Person Submitting Application

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

JUNE 05, 2024

Date

Board Use Only	Date Received: 6/13/24	Amount: $1000 - CK 12740

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
MAKO SURGICAL CORP.
3365 ENTERPRISE AVE
Weston, FL 33331
Registration Number: 3017410889
FEI Number*: 3005985723
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP.[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Dervillia Murphy
Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430
Phone: 201-8315113

verified
M.H 6/14/24

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

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Page Last Updated: 05/20/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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U.S. Department of Health & Human Services

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
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   start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

Officer List with Percentage Owned

	Name	Title	Role	Percent Owned
Mako Surgical Corp.	Cedron, Andres	Officer	Officer	0%
Mako Surgical Corp.	Stiles, Spencer S.	Director & President	Officer & Director	0%
Mako Surgical Corp.	Berry, Jr., William	Director	Director	0%

Please note that Andres Cedron left the company unexpectedly in April 2024. A replacement for his role has yet to be made.

MAKO Surgical Corp.

Ownership List with Percent Owned

Stryker Corporation	100%

Incorp State Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MAKO SURGICAL CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MAKO SURGICAL CORP." WAS INCORPORATED ON THE TWELFTH DAY OF NOVEMBER, A.D. 2004.

Jeffrey W. Bullock, Secretary of State

3880868 8300

SR# 20241774592

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

Authentication: 203377142

Date: 05-01-24

Nevada Section 2: History of Company

Qualifiers:

3: Applicant does not manufacture/distribute pharmaceuticals.

4: Applicant does not manufacture/distribute controlled substances.

FL Home State
Permit Not Required

From: Burnett, Rebecca <Rebecca.Burnett@myfloridalicense.com>
Sent: Wednesday, April 5, 2023 9:45 AM
To: Kelly DiBattista, Esq. <kelly.dibattista@pharma.solutions>
Cc: Alday, Dawn <Dawn.Alday@myfloridalicense.com>
Subject: RE: Resident Manufacturer rX Devices

Caution: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe. When in doubt, contact your IT Department

Good Morning Ms. Dibattista,

Thank you for reaching out to the Division. While we strive to assist permit holders and applicants as much as possible, the Division is unable to provide any binding legal guidance. A permit is not required from our office to distribute a devise. Chapter 499, F.S. outlines when a license is needed.

A Declaratory Statement is the sole means for obtaining a binding interpretation or opinion from the Division of Drugs, Devices and Cosmetics concerning the applicability of statutory provisions, rule or orders over which the Division has authority (Chapters 499, Florida Statutes and Chapter 61N-1, Florida Administrative Code). Refer to Section 120.565, Florida Statutes and Chapter 28-105, Florida Administrative Code, which sets out the requirements for a Petition for Declaratory Statement.

Rebecca

From: Kelly DiBattista, Esq. <kelly.dibattista@pharma.solutions>
Sent: Wednesday, April 5, 2023 7:54 AM
To: Alday, Dawn <Dawn.Alday@myfloridalicense.com>
Subject: RE: Resident Manufacturer rX Devices
Importance: High

[NOTICE] This message comes from a system outside of DBPR. Please exercise caution when clicking on links and/or providing sensitive information. If you have concerns, please contact your Knowledge Champion or the DBPR Helpdesk.

Hi Dawn,

I wanted to circle back on this as my client is attempting to apply for nonresident licenses and the Boards are requesting some sort of proof re: Florida not requiring a license for prescription devices that do not contain a drug. That was my understanding as far as Florida's stance on manufacturers and wholesalers but I wanted to confirm nothing has changed and whether Florida will issue some sort of formal memo. Thanks!

Kelly DiBattista, Esq., Research Director
email: kelly.dibattista@pharma.solutions
office: 484-800-1863 direct: 610-298-5406



This email may be confidential and privileged. If you have received this communication in error, please do not forward it to anyone else, please erase all copies and attachments, and please let me know that it has gone to the wrong person. The above terms may reflect a potential business arrangement, are provided solely as a basis for further discussion, and are not intended to be and do not constitute a legally binding obligation. No legally binding obligations will be created, implied, or inferred until an agreement in final form is executed in writing by all parties involved. This communication additionally does not create or imply an attorney-client relationship or privilege.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

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

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

PRODUCER Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	CONTACT NAME: PHONE (A/C. No. Ext): (866) 283-7122 FAX (A/C. No.): (800) 363-0105 E-MAIL ADDRESS:
INSURED Stryker Corporation & Subsidiaries 1941 Stryker Way Portage MI 49002 USA	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A: Old Republic Insurance Company 24147 INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $100,000 Excluded $2,000,000 $3,000,000 $3,000,000
A	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY [X] Phys Dmge-Self Insd			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION						EACH OCCURRENCE AGGREGATE	
A A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [N] N/A If yes, describe under DESCRIPTION OF OPERATIONS below			MWC31274324 AOS MWXS31274524 Excess WC - MI SIR applies per policy terms & conditions	02/01/2024 02/01/2024	11/01/2024 11/01/2024	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $1,000,000 $1,000,000 $1,000,000

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

FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570103677315

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Mako Surgical Corp. MDEG License # (if applicable): not applicable
Physical Address: 3365 Enterprise Ave
City: Weston State: FL Zip: 33331
Mailing Address (if different from physical address): same as physical address
City: State: Zip:
Telephone: 954-927-2044 Website: www.stryker.com
Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Fernando Middle: N/A Last: Santana
Alias(es, nicknames, name changes, etc.): Fernando Santana Hernandez
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X
Mailing Address: [redacted]
City: Miami State: FL Zip: 33177
Telephone: 954-927-2044 Email: statelicensing1@stryker.com
Are you a citizen of the United States? ☑ Yes ☐ No

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Puerto Rico, Mayaguez Campus		08/89-07/96	
Address	**City**	**State**	**Zip**
259 Avenida Alfonso Valdes Cobian	Mayaguez	PR	00680
Diploma/Degree obtained, if any			
Bachelors of Science, Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Colegio San Ignacio de Loyola		06/83-05/89	
Address	**City**	**State**	**Zip**
Urb Santa Maria, 1940 Calle Sauco	San Juan	PR	00926
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/23 - Present	[redacted] SW 163rd Terrace	Miami	FL	33187
05/22-12/23	[redacted] NW 53rd Street Apt 211	Doral	FL	33166
03/21-05/22	[redacted] NW 53rd Street Apt 309	Doral	FL	33166
06/18-03/21	[redacted] W 1st Avenue Apt 2207	Miami	FL	33130
01/17-06/18	[redacted] vernia Street Apt Apt 410	West Palm Beach	FL	33401
01/16-01/17	[redacted] ourtenay Court	Jupiter	FL	33458
03/13-12/15	[redacted] 1 SW 39th Street	Miramar	FL	33029
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Mako Surgical Corp			8/2018 - Present	
Business Address		**City**	**State**	**Zip**
3365 Enterprise Ave		Weston	FL	33331
Phone	**Title**		**Number of Employed Hours**	
954-927-2044	Sr. Quality Assurance Manager		11,000+	
Description of Duties				
See attached resume				

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

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

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

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

Continue on next page if additional space is needed.

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

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

FERNANDO SANTANA

Original Signature (electronic, copies or stamps not accepted)

JUNE 05, 2024

Date

I, Fernando Santana, **certify that as the MDEG Administrator for**

Mako Surgical Corp.,

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

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

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

Fernando Santana
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

JUNE 05, 2024
Date

Board Use Only	Date Received: 6/13/24

Fernando Santana

[redacted]NW 53RD STREET APT 211, DORAL FL 33166
[redacted]

Executive Summary

Highly qualified quality leader with more than twenty years of experience in the quality engineering and assurance fields. Have experience in quality control, quality engineering, process development, design controls, operations quality management and supplier quality management. Possess great communication and problem-solving skills.

Core Qualifications

- Quality management
- Design controls
- Analytical skills
- Project management
- Quality engineering
- Change management
- Industrial engineering
- Problem resolution

Professional Experience

8/2018 – Present

Stryker Corporation Weston, FL

Sr. Quality Assurance Manager - reports to Quality Director

Manage execution of all quality operations activities for the site (responsible for quality control, quality engineering (operations and suppliers)). Establish budget and goals for quality operations department in support of manufacturing of orthopedics robotic systems, instruments and disposables medical devices.

Accomplishments:

- Established site quality kpi's to be in alignment with corporate goals.
- Facilitated external audits for all quality operations QMS elements and have achieved zero external quality operations audit findings for all audits to date.
- Achieved reduction in product escape non-conformances in 2020-2021 versus 2019 (and also reduction versus 2018).
- Reduced average internal and external (suppliers) non-conformance record aging, thus consistently meeting NC aging kpi's.
- Reduced average internal and external CAPA record aging and have consistently since then met CAPA aging and effectiveness kpi's.
- Reduced quarantine inventory in 2021.
- Reduced RI inspection capacity needs in 2021 via supplier certifications and receiving inspection optimization initiatives.
- Managed execution of quality operations QMS deliverables for a company M&A to Stryker.

1/2016 – 8/2018

Zimmer Biomet 3i Palm Beach Gardens, FL

Supplier Quality Dental Division Leader - reported to Quality Director

Manage execution of all supplier quality activities for the Palm Beach Gardens, FL and Valencia, Spain sites (responsible for execution of supplier qualifications, audits, performance monitoring, change management and corrective actions of approximately 500 suppliers).

Accomplishments:

- Successfully completed site alignment to new corporate procedures for supplier quality (including implementation of PPAP+).
- Enhanced purchasing controls process for manufacturing materials.
- Successfully managed execution of supplier quality deliverables for product transfers as part of the integration between Zimmer and Biomet.
- Enhanced metric trending plans for receiving inspection non-conformances and triggers for supplier corrective actions.
- Re-engineered supplier corrective action process and reduced SCAR aging and thus met SCAR aging kpi's.
- Improved lot acceptance rates across both dental sites in 2017 by implementing systemic solutions.

9/2013 - 12/2015

Biomet 3i Palm Beach Gardens, FL

Plant Quality Manager - reported to Quality Director

Manage execution of all quality operations activities for the site (responsible for quality control, quality engineering, supplier quality, calibration and microbiology/sterilization).

Accomplishments:

- Re-engineered the product non-conformance system and created a quality hold process in accordance with QSR and ISO 13485 requirements.
- Collaborated with other functional managers to re-engineer other production and process control processes, including calibration and process validation processes.
- Established metric trending plans to track and trend quality systems performance.
- Reduced the number of open non-conformances between 2014 and 2015.

2/2012 - 9/2013

MAKO Surgical Davie, FL (currently part of **Stryker Corporation**)

Software Validation Engineer (Contract position)

Leading development, validation and implementation activities of a risk management electronic process that will be used to develop requirements and testing documents as part of a Design Control.

Accomplishments:

- Worked with cross-functional team to develop document content and relationships for risk documents (Hazard Analysis, FMEA's and Software Risk Analysis) in accordance to ISO 14971, IEC 62304, IEC 62366 and IEC 60601-1.
- Supported validation and implementation activities of electronic process for requirements and test documents.

2000 - 2011

Boston Scientific Miami, FL (2000 – 2011)

2009 -2011

Senior Quality Manager - reported to Quality Director
Reason for moving – Boston Scientific closed the Miami plant.

Managed execution of quality engineering deliverables for the corporate strategy of outsourcing of core wire sub-assembly processes (including grinding, straightening and coating) to five different suppliers as part of the Miami site closure (promoted to Senior Manager in 2011).

Accomplishments:

- Developed and managed execution of quality planning strategy for outsourcing project.
- Effectively managed application of newly developed supplier process control systems.
- Applied learnings from 1st phase of project to 2nd phase of project, resulting in zero out of spec conditions during final product performance testing.
- Acting member of site's internal audit team.
- One of the site's process validation specialists.

Boston Scientific Miami, FL

2008 – 2009

Quality Manager - reported to Quality Director

Managed quality engineers, supervisors, technicians and inspectors who supported operations value streams (cardiovascular products in 2008 and site sub-assemblies in 2009).

Accomplishments:

- Sub-assembly value stream achieved quality incident reduction, ship hold reduction, zero ineffective or overdue CAPA's and line clearance non-conforming event (NCE) reduction from previous year, while reducing NCE disposition cycle times by embedding a real-time investigation culture within value stream while also achieving operational fill rate and financial goals.
- Cardiovascular value stream achieved quality incident reduction, line clearance NCE reduction and manufacturing-related customer complaints from previous year, while achieving operational service and financial goals.
- Effectively supported site-wide CAPA initiatives (labeling/packaging master branding and line clearance system improvements).
- Selected as one of the site CAPA independent reviewers to ensure that CAPA root cause investigations were technically sound, thus improving effectiveness of CAPA's.

Boston Scientific Miami, FL

2007 – 2008

Principal Quality Engineer

Provided quality engineering direction and mentoring for Process Validation Remediation (PVR) team and (2) supported the validation and verification activities for PVR project.
Accomplishments:

- Mentored quality, process development and manufacturing engineers in process validation (PV) and test method validation (TMV) activities.
- Developed Master Validation Plans and Product Performance validation protocols.
- Developed strategy for alignment of Process FMEA documents to Product Risk Analysis Workbooks (Design FMEA's).
- Applied sound, problem-solving methods to identify, prioritize, communicate, and resolve process validation failures.

Boston Scientific Miami, FL

2002 – 2007

Senior Quality Engineer

Successfully executed quality engineering activities, while working with team members from other functional areas, for new product and process introduction of five new guidewire products. In this role, acted as one of the site's Subject Matter Experts for Design Controls, Risk Management, Process Validations and Statistics.

Boston Scientific Miami, FL

2000 – 2002

Quality Engineer

Performed quality engineering support for the casting and molding departments and executed quality engineering activities for transfer-in of non-CV guidewire product families to the Miami plant, including transfer of the two highest-volume product lines. Main responsibilities included execution of due diligence, review of new work instruction and validation protocols and reports, as well as development and validation of test methods.

1996 - 2000

Pall Biomedical Inc. Fajardo, P.R.

Manufacturing Engineer

Executed manufacturing engineering and quality engineering activities to support the manufacturing and packaging processes of medical filters. Main activities included execution of process validations, cost reduction projects and internal / external product non-conformance investigations.

Education

1997

University of Puerto Rico, Mayaguez, Puerto Rico, USA.

Bachelors of Science in Industrial Engineering

Related coursework: Statistics, Design of Experiments and Statistical Quality Control

Training

- LEAD – 100 Management Fundamentals Global Program (Stryker) (2019)
- Six Sigma Yellow Belt Training (Zimmer Biomet) (2016)
- Project Management for Professionals (PMP) Certification (Baker University) (2011)
- People First Leadership Development Program (Lannon Worldwide) (2009)
- ISO 9001:2008 Lead Auditor with Emphasis on ISO 13485:2003 (BSI Training) (2009)
- Overview of ISO 13485: 2003, JPAL and the MDD (BSI Training) (2009)
- PALM I Strategy Execution & Finance for Non-Financial Executives (AMA Training) (2009)
- Leadership Development Program (People First Training) (2009)
- The 7 Habits of Highly Effective People - Introductory Workshop for Associates (2008)
- Six Sigma Black Belt Training (Boston Scientific) (2005)
- Six Sigma Yellow Belt and Green Belt Training (Boston Scientific) (2004)
- Fulton Findings' Weibull/Lognormal Seminar (2000)
- SPC Training (1998)
- Design Control/Validation Academy (1997)
- Quality System Regulations (GMP's) (1996)

Awards

- CAPA Gold Award (2010)
- CAPA Gold Award (2008)

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Mako Surgical Corp.

Pharmacy/Wholesaler License # (if applicable): not applicable

Physical Address: 3365 Enterprise Ave

City: Weston State: FL Zip: 33331

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

City: State: Zip:

Telephone: 954-927-2044 Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Fernando Middle: N/A Last: Santana

Alias(es, nicknames, name changes, etc.): Fernando Santana Hernandez

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

Mailing Address: [redacted]

City: Miami State: FL Zip: 33177

Telephone: [redacted] Email: fernando.santana@stryker.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Puerto Rico, Mayaguez Campus		08/89-07/96	
Address	**City**	**State**	**Zip**
259 Avenida Alfonso Valdes Cobian	Mayaguez	PR	00680
Diploma/Degree obtained, if any			
Bachelors of Science, Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Colegio San Ignacio de Loyola		06/83-05/89	
Address	**City**	**State**	**Zip**
Urb Santa Maria, 1940 Calle Sauco	San Juan	PR	00926
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/23 - Present	[redacted] SW 163rd Terrace	Miami	FL	33187
05/22-12/23	[redacted] W 53rd Street Apt 211	Doral	FL	33166
03/21-05/22	[redacted] W 53rd Street Apt 309	Doral	FL	33166
06/18-03/21	[redacted] 1st Avenue Apt 2207	Miami	FL	33130
01/17-06/18	[redacted] ernia Street Apt Apt 410	West Palm Beach	FL	33401
01/16-01/17	[redacted] urtenay Court	Jupiter	FL	33458
03/13-12/15	[redacted] SW 39th Street	Miramar	FL	33029
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Mako Surgical Corp			8/2018 - Present	
Business Address		**City**	**State**	**Zip**
3365 Enterprise Ave		Weston	FL	33331
Phone	**Title**		**Number of Employed Hours**	
954-927-2044	Sr. Quality Assurance Manager		11,000 +	
Description of Duties				
See attached resume				

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

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

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

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

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? Not applicable		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Fernando Santana, **certify that as the designated representative for**

Mako Surgical Corp.,

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

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

Fernando Santana
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

JUNE 05, 2024
Date

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

Fernando Santana
Print Name (First, Last)

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

JUNE 05, 2024
Date

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

State of Florida, ss. County of Broward

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

F. S.
Original Signature

JUNE 05, 2024
Date

Subscribed and Sworn to before me this 5th day of June 2024.

Notary Public Signature

JESUS MANUEL MEDINA
Notary Public - State of Florida
Commission # HH 116240
My Comm. Expires Jun 30, 2025
Bonded through National Notary Assn.

(Seal)

Weston, FL Employees

CONFIDENTIAL

Preferred Name
AARON CHIN
Aaron Kaplan
Abraham Monzon
Akire Green
Alain Gehy
Alejandro Collazos
Alessandra Chavez
Alex Chin
Alexander Hutson
Alvaro Cepeda
Amanda Miller
Anais Palmer
Andre Parcells
Andrew Meyer
Andrew North
Andrew Russell
Angelica Munoz
ANGELINA DORMAN
Angelo Valdes
Anthony Carlucci
Antonios Pandis
Anum Bartolotta
Armando Enrique
Arshiya Choudhary
Ashley Bedgood
Ashley Walters
Benton Reynolds
Brandon Hogarth
Brandon Vazquez
Brendan Smith
Brian Patchen
Brianna Woods
Briasha Burgos
Brittany Pichler
Caitlin Raymond
Cameron McFarland
Carlos Collazo
Casey Chang
Chanika Tirogene
Charlene Vidal
Chenel Johnson
Christian Reyes

Christian Rodriguez
Christian Vargas
CHRISTIAN WRIGHT
Christopher Cosie
Christy Cuttino
Claudia Pinochet Alba
Clay Littleton
Clayton Odor
Cortney Alexis
Dani Guevara Huynh
Daniel Segui
Deanna Reynolds
Deborah Johnson
Devoy Grey
Diana Arenas
DIANA PATINO FERREIRA
Diego Vidal
Don Todd
Donnette Harriott
Eddie Bolano
Eric Boyer
Evgeni Bonchev
Fernanda Lewinsky
Francisco Calvo
Francisco Pozzo
Franco Melis
Fred Coll
Frederick Kundert
Gabriella Durand
Gabrielle Rivera
Gail Saintil
Georgette Marshall
Gessica Suffy
Gilbert Chiuz
Gina Gautieri
Grace Vernon
Guy Merus
Hanna Robla
Ivonne Mesa
Izza Khan
Jameson Offerdahl
Jason Dodds
Javier Diaz

Jazmine Buggs
Jeremy Devine
Jessie Greatorex
Joemy Fermaintt
Jose Campana
Jose Matos
Joshua Gardner
Joshua Grant
Kaitlyn Morris-Sturgis
Kalie Brumbaugh
Kate Savage
Kathryn Walter
Kayla Thompson
Kevin Altamirano
Kira Theodore
Kristopher Keimel
Krystal Rivera
Kyante Belvin
Laura Sanchez
LEO MIRANDA
Leonard Correa
Lester De La Paz
Licha Scott
Linda Rivera
Luis Diaz
Luz Arocho
Manushka St. Felix
Marcus Edwards
Maria Aguero
Maria Padron
Mariana Gutierrez
Mariella Cefalo
Maritza Sanchez Veras
Marlene Santiago
Martin Kareff
Maylasia Mapps
Melissa Ho Fung
Melody Chan
Melody Peres
Mohammed Hasan
Nancy Ramirez
Natalie Lovett
Natalie Marrero

Natasha Quallo
Nattamon Phochachan
Nesa Verneret
Nicardo Lindsay
Nichelle Toylar
Nicholas Alayo
Nicolas Martinez
NICOLE CASTANEDA
Nika Lubin
Noorin Iqbal
Ommeed Shahrokh
Pamela Rolle
Paula De La Plaza Abreu
Peter Anderson
Rae'Torria Bailey
Rafael Cabral
Rebeca Quintero Padilla
Renee Wolowitz
Roger Chisholm
Ronique Thomas
Ruddy Maria
Rudy Taveras
Sara Hanooman
Sean Harris
Selene Marcano
Shail Parikh
Shelly Grocher
Shivan Vyas
Sofia Mendoza
Sophia Mahlke
SOPHIA MCKINLEY
Stacey Capilos
Stan Richetti
Sy Chandra
Tavares Walters
Thea Harvey
Thomas Barreca
Tori Kirkland
Tracy Smith
Tyler Johnson
Tyler Watson
Unitheia Rolle
Valantou Dovellos

Valentina Fernandez
Valeria Grisales
Vanessa Lalanne
Verdi Mayer Soto
Wael Hazin
Waleed Akhtar
Willie Ramirez
Roula Sanaallah (1001017)
Alyssabeth Tremblay (1001166)
Samer El Sadani (1001280)
Katherine Ruiz (1001417)
Michael Messiha (1001892)
Regan Ora (1003772)
Teresa Vasanski (1003811)
Jia Li Ma (1004134)[C]
Maria Montoya (1004527)
Angie Dejoie (1004626)
Ingrid Negron (1004680)
Hector Rivera (1005053)
Joey Lin (1006578)
Juliana Gomez (1007212)
Alyssa Viness (1007759)
Adam Nagy (1008620)
Macartney Johnson (1009044)
Carlos Lumbre (1009106)
Jason Mitchell (1009592)
Melissa Goude (1009654)
Vivian Llorca (1009877)
Nelson Baez (1009890)
Ruben Martinez (1009891)
Brett Hernandez (1010164)
Samuel Michel (1010430)
Joseph Zeichman (1010647)
Sergio Vargas (1011002)
Nicholas Canada (1011064)
LUIS BRIGNONI (1011220)
Mehul Patel (1012630)
Steven Knabe (1012886)
Jose Lopez-Sandin (1014090)
Kevin Knox (1014545)
Mario Abreu (1015645)
Abigail Brinson (1015749)
Mario Maldonado (1016577)

Katie Li (1016616)
Jolina Muma (1016954)
Lawrence Fox (1019165)
Laritza Machin (1019512)
Aidee Herrera (1019543)
Karthik Kunnam (1019633)[C]
Gian Avendano (1020231)
Elias Kushner (1020265)
Julio Martinez-Vazquez (1020272)
Ricardo Molina (1020279)
Gerardo Vargas (1020304)
ALVARO ZAVALETA (1020312)
Lazaro Romero (1020689)
Joshua Vega Calderon (1021135)
Christian Monterrey (1021914)
Anusha Lingam (1021937)
Alexis Amechi (Terminated) (1022638)
Brianna Jeanty (1027023)
Allan Fuerte (1027111)
SOFIA HENRIQUEZ (1027317)
Ralph Jeanphilippe (1027829)
Miguel Santa Barbara (1027966)
Stephanie Minott (1028005)
Jacqueline Ferrara (1029114)
Theodore Cole (1029674)
Lenin Larez (1030162)
Alexander Malaty (1030184)
Wilmarie Camacho Dones (1030666)
Waleska Bonilla (1030670)
Siva Kethineni (1030765)[C]
Rachana Kandel (1030769)[C]
Lei Sun (1031663)
AIDA SUAREZ (1031810)
Iris Bahri (1031965)
Viral Patel (1032568)[C]
Stephen Scripp (1033076)
Grant Elgin (1033168)
David Bat (1033609)
Jailla Jefferson (1033751)
Rafael Perez RP (1033941)
Jevaugh Pinnock (1033976)
Alex Atala (1034290)

Joe Prinke (1034467)
Nikhal Nixon (1035066)
Kimia Mahboub (1035325)[C]
Nicholas McKennon (1037360)
Ana Paz (1037502)
SALLY-MAE BRAUTIGAM (1037664)
Sebastian Vengoechea (1037670)
Mariamalia Rodriguez (1037898)
Roderick Pender (1037899)
Nirida Villegas (1038593)
Marina Abraam (1039761)[C]
Hallie Bucher (1040433)
Andy Bledsoe (1040468)
Quentin Wedderburn (1041464)
Casey Shaw (1042156)
Gabriel Pereda (On Leave) (1043301)
Natalia Amancio (1043686)
Nelson DeLeon (1044542)[C]
Kaitlyn Christensen (On Leave) (1047066)
Narmer Vargas (1047453)
Colton Burgos (1048068)
Chris Victor David (1048539)
Aaron Stegall (1053107)
Joely Pagan (1056175)
Wilmer Rodriguez (1057924)
Natasha Williams (1058094)
SYDNEY KNOLL (1058250)
Sausan Kaddah Pizarro (1058846)
Ricardo Zapata (1059183)
Dewey Owens (1059361)[C]
Gabriela Hernandez (1059623)
Adnaloy Villares (1059671)[C]
Hector Rodriguez (1059902)
Jonathan Bandel (1062208)
Varsha Venkatapathy (1062552)
Evan Su (1062701)
Stephanie Hanks (1062892)[C]
Chanel Binger (1062986)[C]
Dylan Prysock (1063052)
Ayushi Elhence (1063248)
Paula Lugo (1063439)
LaTanya McGriff (1063529)[C]

Aimee Garcia (1063640)[C]
Javier Gandulla (1063780)[C]
Rafael Ontiveros (1063813)
Alex Wilhelm (1063914)
Cirilo Aday (1064000)[C]
Aaron Wu (1064376)
Natalie Corrales (1064421)
Andreina Castillo (1064762)
Nicholas Fajardo (1064841)
Peter Joseph (1065641)[C]
Gipsy Pereiras (1065705)
Morgan Armstrong (1065858)
Emmanuel Jaquez Castillo (1066304)[C]
Shea Morrissey (1372865)
Wendy Scott (1372871)
Matthew Paul (1458349)
Giovanny Rivera (1459254)
Marino Vizcaino (1459670)
Rafael Valdes (1460869)
Christopher Lopez (1460952)
Adrian Nolan (1469793)
Maricelli Vazquez Gonzalez (1492329)
Valerie McCarthy (1497507)
Franki Espinal (1674763)
Omayra Pinto Perez (2081139)
Ben Schwer (2339379)
RONALD NANDA (3063418)
Luis Horta (3247834)
Juan Morales (3272053)
Sean Walling (3324776)
Edith Perez Criollo (3324784)
Jairo Cepeda (3324790)
Alpesh Mistry (3324809)
Michael Basileo (3324819)
Dan Eng (3324898)
John Simon (3324969)
Luis Guevara (3324988)
Marlon Nunez (3325042)
Jorge Rivera (3332359)
Socrates Cedeno (3332447)
Sarah Olker (3564354)

Cesar Gamarra (4525787)
Pramodh Joseph (4821786)
Adriana Green (5299786)
Salman Zahid (5412786)
Reny Rosales (5482786)
Joal Lobusta (5547786)
Holly Kennedy (6172787)
Andrea Lara (6515842)
Ezequiel Zapata (6572838)
Emmanuel Coloma (6584832)
Jia Huang (6602841)
Luis Cuenca Escalona (6602845)
Tim Vonderlinden (6838833)
Krisi Rotondelli (6889954)
Greta McCarthy (6960058)
Ercan Bezan (6962944)
Michael Casado (6986985)
Miguel Gomez (7047083)
Nilton Cespedes (7052046)
Carlos Cardenas (7064116)
Jarlen Suero (7070069)
Rafael Fernandez (7101221)
Kervins Bienaime (On Leave) (7101351)
Alex Beauboeuf (7101414)
Ivette Freixas (7101419)
Alexa Guell (7101420)
Jose Gibaja (7123256)
Paul Duran (7126296)
Cara Berner (7130228)
Margot Senac (7165185)
Kelsey Harris (7169260)
Jeremy Johnson (7180201)
Alinson Dumorne (7187687)
Whitney Ng (7187878)
Zena Khan (7188621)
Fernando Santana (7189292)
Ariel Diaz (7190179)
Mark Szober (7190580)
Nia Olivo (7192079)
Marissa Foreit (7192462)
Rafael Charpentier Saborio (7193735)

Javier Gonzalez (7194553)
Aubrey Lee (7195813)
Luis Hincapie (7196213)
Carlos Chaves (7196506)
Angela Henao (7239243)
Jorge Cortes (7243250)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

OR

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

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,270	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,848	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,189	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	59	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2018
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,103	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	$ 3,888	$ 2,841	$ 2,584	$ 2,223	$ 2,713
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	$ 3,673	$ 2,683	$ 2,281	$ 1,954	$ 2,562
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

4G

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

Section 1: General Information

Facility Name: Mobius Imaging, LLC

Physical Address: 2 Shaker Road, Ste F100

City: Shirley State: MA Zip: 01464

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 978-615-5024 Website: www.stryker.com

Name of Designated Representative (DR): Daniel Doucette

Licensing Company Email: statelicensing1@stryker.com DR Email: daniel.doucette@stryker.com

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2 April 2024
Date

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

Name: Not Applicable-no pharmaceutical products
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE
Parent Company (if any): Loon Intermediateco, LLC and then publicly traded Stryker Corporation (SYK)
Corporation Name: Mobius Imaging, LLC
Mailing Address: 2 Shaker Road, Suite F100
City: Shirley State: MA Zip: 01464
Telephone: 269-385-2600 Email: austin.ke@stryker.com
Contact Person Name: Austin Ke

Date of SEC Registration: 1979	SEC Registration Number: 001-13149	Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

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

Section 6: Partnership

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

Section 7: Sole Owner

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

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

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

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

Mobius Imaging, LLC

Facility Name

Daniel Doucette

Print Name of Authorized Person Submitting Application

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

2 APRIL 2024

Date

Board Use Only	Date Received: 4/5/24	Amount: $1000-ck 12697

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
MOBIUS IMAGING, LLC
2 Shaker Road
Suite F100
Shirley, MA 01464
Registration Number: 3010151377
FEI Number*: 3010151377
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Oonagh Lahiff
2 Pearl Ct
Allendale, NJ 07401
Phone: 001-201-8243302

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

verified
M.H 6/6/24

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

Page Last Updated: 05/13/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MOBIUS IMAGING, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MOBIUS IMAGING, LLC" WAS FORMED ON THE ELEVENTH DAY OF JULY, A.D. 2008.

Jeffrey W. Bullock, Secretary of State

4573949 8300

SR# 20241774690

Authentication: 203377177

Date: 05-01-24

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

FW: Confirmation Request on Licensing Requirement

Mary Springer <mary.springer@pharma.solutions>
Wed 9/22/2021 4:27 PM
To: Maria Pennings <maria.pennings@pharma.solutions>; Shreya Gandhi <shreya.gandhi@pharma.solutions>

From: Chow, Joanna (DPH) <joanna.chow@state.ma.us>
Sent: Wednesday, September 22, 2021 2:14 PM
To: Mary Springer <mary.springer@pharma.solu ons>
Subject: RE: Confirma on Request on Licensing Requirement

The Massachusetts Board of Pharmacy does not license Resident wholesalers. Except for outsourcing facilities, the Massachusetts Board of Pharmacy does not offer any out of state licenses at this time.

Please review the Massachusetts Drug Control Program website to see if a license would be required through them and contact them directly with any further questions: https://www.mass.gov/orgs/drug-control-program
Phone: (617)793-0800
Email: dcp.dph@massmail.state.ma.us

Thank you,

Joanna Chow
Office Support Specialist I
Board of Registration in Pharmacy
Department of Public Health
Bureau of Health Professions Licensure
239 Causeway Street, Suite 500
Boston MA, 02114
Tel: 617-973-0952
Fax: 617-973-0980

In the near future, the Board of Registra on in Pharmacy will begin sending renewal reminders for Pharmacists and Pharmacy Technicians ONLY by email and NOT by US mail. To receive your renewal reminder, please make sure we have a working email address for you. You may update your email address and any other contact informa on by using the following link. Login (mylicense.com)

From: Mary Springer <mary.springer@pharma.solutions>
Sent: Wednesday, September 22, 2021 2:00 PM
To: Chow, Joanna (DPH) <Joanna.Chow@mass.gov>
Subject: RE: Confirmation Request on Licensing Requirement

CAUTION: This email originated from a sender outside of the Commonwealth of Massachusetts mail system. Do not click on links or open attachments unless you recognize the sender and know the content is safe.

Hello Ms. Chow,

Officer List with Percentage Owned

	Name	Title	Role	Percent Owned
Mobius Imaging, LLC	Cedron, Andres	Officer	Officer	0%
Mobius Imaging, LLC	Pierce, J. Andrew	Officer	Officer	0%

Please note that Andres Cedron left the company unexpectedly in April 2024. A replacement for his role has yet to be made.

Mobius Imaging, LLC
Ownership List with Percent Owned

Loon Intermediateco, LLC	100%

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

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

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

PRODUCER Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	**CONTACT NAME:** **PHONE (A/C, No, Ext):** (866) 283-7122 **FAX (A/C, No.):** (800) 363-0105 **E-MAIL ADDRESS:**

INSURER(S) AFFORDING COVERAGE		**NAIC #**
INSURER A:	Old Republic Insurance Company	24147
INSURER B:		
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER							
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	Y/N			AOS				
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A		MWXS31274524	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
	(Mandatory in NH)			Excess WC - MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

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

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570103677315

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2 Shaker
Doucette

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Mobius Imaging, LLC

Pharmacy/Wholesaler License # (if applicable) Not applicable

Physical Address 2 Shaker Rd Suite F100

City Shirley State MA Zip 01464

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

City _____ State _____ Zip _____

Telephone 978-615-5024 Website www.stryker.com

Licensing Company Email statelicensing1@stryker.com

Section 2: Personal Information

First Daniel Middle Vincent Last Douctte

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

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

Mailing Address [redacted] Lamplighter Lane

City North Chelmsford State MA Zip 01863

Telephone 978-615-5024 Email statelicensing1@stryker.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Southern New Hampshire University		07/22-Present	
Address	**City**	**State**	**Zip**
2500 N River Rd	Manchester	NH	03106
Diploma/Degree obtained, if any			
BS Operations Management with a concentration in Logistics and Transportation Competion (May/June 2025)			

School Name		From - To (MM/YY – MM/YY)	
Northeastern University		01/89-01/91	
Address	**City**	**State**	**Zip**
360 Huntington Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
Certificate in Transportaton and Physical Distribution Management			

School Name		From - To (MM/YY – MM/YY)	
Wakefield High School		9/80-6/84	
Address	City	State	Zip
60 Farm Street	Wakefield	MA	01880
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/23-present	[redacted]amplighter Lane	North Chelmsford	MA	01863
4/19-7/23	[redacted]ittleton Road Unit 2C	Ayer	MA	01432
12/18-4/19	[redacted]d Towne Road	Ayer	MA	01432
07/16-12/18	[redacted] Laurence street	Clinton	MA	01510
05/08-07/16	[redacted]Manchester St	Lowell	MA	01852
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name		From - To (MM/YY – MM/YY)	
Mobius Imaging, LLC		2014-Present	
Business Address	**City**	**State**	**Zip**
2 Shaker Road, Ste F100	Shirley	MA	01464
Phone	**Title**	**Number of Employed Hours**	
978-615-5024	Sr Logistics Manager	18,000+	
Description of Duties			
See attached Resume			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

RLV Duckett

Original Signature (electronic, copies or stamps not accepted)

2 April 2024

Date

I, Daniel Doucette, **certify that as the designated representative for**

Mobius Imaging, LLC,

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

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

Daniel Doucette
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2 APRIL 2024
Date

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

Daniel Doucette

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2 April 2024

Date

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

State of Massachusetts, ss. County of Worcester

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

Original Signature

2 April 2024

Date

Subscribed and Sworn to before me this 2nd day of April.

Rob Joseph Ricciuti

Notary Public Signature

ROSS JOSEPH RICCIUTI
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
AUGUST 31, 2029
Seal

DANIEL DOUCETTE

[redacted]ittleton Rd ▣ Ayer MA, 01432 ▣[redacted]

Senior Logistics Manager leveraging expertise in domestic and international shipping regulations as well as resource management and strategic planning to coordinate on-time delivery of large-scale distributions for complex products. Creates bottom-line benefits through diligent negotiations, rigorous cost controls, and continuous improvement projects.

Global logistics planning spans Europe, Asia, the Middle East, and the Americas

- Collaborated with project managers to direct logistics for a $16M cargo screen project in Saudi Arabia.
- Coordinated international distribution of Explosives Detection Systems for DOD embassy's around the world.
- Achieved an average of 10% savings by negotiating domestic and international shipping rates for a startup company.
- Managed shipment of over 300 CT X-ray systems domestically and internationally.

Education & Credentials

BS, Supply Chain Management (in progress) – NORTHEASTERN UNIVERSITY,
Certified in Transportation & Physical Distribution Management

Expertise includes: •Export Compliance •Imports• MRP Programs • Windows • MS Office • Access • PowerPoint •Security Systems • ISO 9000 • Regulatory

Professional Overview

Sr. Logistics Manager/Associate Logistics Manager — MOBIUS IMAGING/STRYKER: 2014-Present

- Built and established the logistics department. Obtained official product classification with the US Department of Commerce.
- Handled all import and exports related needs.
- Work with materials department, supplier shipping terms, contracts, and reviewed company insurance policy.
- Work with Trade Compliance, and Regulatory, collaborate with Enterprise Planning and Logistics Operations.
- Managed the shipping and receiving and transfer of inventory
- Acting Facilities Manager, built out a new manufacturing facility and multiple expansions.
- Acting Security responsibilities, cameras, card reader, access badges, Stryker Security for Shirley MA Facility
- Acting, Operations as needed.
- Acted Company IT, tasked with establishing a legitimate server and phone system to accommodate growth.
- Acted as Safety representative, facilitated training, and provided a safe work environment.
- Support sales and marketing and all internal departments and distributors.

Logistics and Distribution Manager — VIKING SYSTEMS, CONMED CORP: (2011-2014)

- Improved the logistics department and distribution network; modified procedures.
- Managed shipping and receiving improving and streamlining urgent end-of-month and quarter orders.
- Handled import and export issues as well as any project or tasks asked.
- Worked with and supported all sales staff and all internal departments.

Logistics Manager, Supply Chain — REVEAL IMAGING, A SAIC COMPANY: (2006-2011)

Led employees in exporting complex Explosives Detection Systems to airports nationwide and globally; managed daily operations, documentation, and export approval as well as the RFP/FRQ process for logistics.

- Built the logistics department for an early-stage company; established procedures and implemented documentation and carnet software for expedited processing.
- Drove a crating cost reduction that resulted in a 60% decrease in labor expense and a $200K annual savings.
- Classified imported products for duty and tax savings; partnered with sales, marketing, and accounting on price quotes, tenders, letters of credit shipments, and import/export regulations.

Logistics Manager, — L3 Communications, ESSCO (2005-2006)

Headed a four-member team in shipping, receiving, and stockroom activities while managing import and export functions.

- Administered large shipments of multiple oversized radomes to remote sites worldwide including Asia Pacific, South America, and the Middle East; shipped hi-tech oversized government antenna vehicles to France.
- Lowered expenditures an average of 20% through logistical competition and proper service selection.

Logistics Manager, L3 Security & Detection System (2001-2004)

Oversaw supply chain and facility needs, coordinating space requirements for offsite storage, establishing shipping processes for returns and international customers, and contributing to business management in various functions.

- Negotiated improved logistics rates that resulted in 11% annual savings.
- Implemented an Access database to record and track shipping activity in three facilities nationwide and trained personnel on export documentation software.
- Obtained 66 Department of State licenses, 7 Department of Commerce licenses, and 7 Commodity Classifications in accordance with commodity jurisdiction policy shifts.

Traffic Coordinator, PerkinElmer/L3 Security & Detection System (1998-2001)

Promoted to direct domestic and international pickups and deliveries and prepare all necessary documentation.

- Captured $30K+ cost savings by introducing export documentation software; created charts and spreadsheets to track cuts in expenditures as well as shipping information.
- Planned and managed trade show logistics in more than ten countries and eight states in the US.
- Supervised facility projects such as sign installations, paving, painting, and internal renovations; closed a trash compactor service agreement that reduced monthly costs by $250.

Shipping/Receiving Specialist, Vivid, PerkinElmer (1994-1998)

Handled shipping and receiving functions for an operation processing 15 airport security systems per month.

- Managed inventory control activities and supervised stock rooms and on-hand materials; performed kitting functions, stocking, and data entry for the MRP system. Initiated the groundwork for establishing a traffic department.

Other: Import/Export Compliance Coordinator, FLIR SYSTEMS: Performed contract review, maintained license tracking through government agencies, and prepared submittals for state and commerce departments.
Veteran US NAVY.

2 Shaker
Doucette

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Mobius Imaging, LLC
MDEG License # (if applicable): Not applicable
Physical Address: 2 Shaker Rd Suite F100
City: Shirley State: MA Zip: 01464
Mailing Address (if different from physical address): same as physical address
City: State: Zip:
Telephone: 978-615-5024 Website: www.stryker.com
Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Daniel Middle: Vincent Last: Douctte
Alias(es, nicknames, name changes, etc.): Not applicable
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X
Mailing Address: [redacted] Littleton Road Unit 2C
City: Ayer State: MA Zip: 01432
Telephone: [redacted] Email: statelicensing1@stryker.com
Are you a citizen of the United States? ☑ Yes ☐ No

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Southern New Hampshire University		07/22 - Present	
Address	**City**	**State**	**Zip**
2500 N River Rd	Manchester	NH	03106
Diploma/Degree obtained, if any			
BS Operations Mangement with a concentration in logistics and Transportation; Completion May/June 2025			

School Name		From - To (MM/YY – MM/YY)	
Northeastern University		01/89-01/91	
Address	**City**	**State**	**Zip**
360 Huntington Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
Certificate in Transportation and Physical Distribution Management			

School Name		From - To (MM/YY – MM/YY)	
Wakefield High School		9/1980 - 6/1984	
Address	**City**	**State**	**Zip**
60 Farm Street	Wakefield	MA	01880
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
7/23 - Present	[redacted]amplighter Lane	North Chelmsford	MA	01863
4/19 - 7/23	[redacted]ttleton Road Unit 2C	Ayer	MA	01432
12/18 - 4/19	[redacted]d Towne Road	Ayer	MA	01432
07/16-12/18	[redacted]Laurence Street	Clinton	MA	01510
05/08-07/16	[redacted]anchster Street	Lowell	MA	01852
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

2 Shaker
Doucette

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

Business Name: Mobius Imaging, LLC			From - To (MM/YY – MM/YY): 2014 - Present	
Business Address: 2 Shaker Rd Suite F100	City: Shirley		State: MA	Zip: 01464
Phone: 978-615-5024	Title: Sr Logistics Manager		Number of Employed Hours: 18,000+	
Description of Duties: See attached resume				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

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

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

16 MAY 2024
Date

2 Shaker
Doucette

I, Daniel Doucette, **certify that as the MDEG Administrator for**

Mobius Imaging, LLC,

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

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

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

Daniel Doucette
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

16 MAY 2024
Date

Board Use Only	Date Received: 05/17/24

DANIEL DOUCETTE

[redacted] ittleton Rd ▣ Ayer MA, 01432 [redacted]

Senior Logistics Manager leveraging expertise in domestic and international shipping regulations as well as resource management and strategic planning to coordinate on-time delivery of large-scale distributions for complex products. Creates bottom-line benefits through diligent negotiations, rigorous cost controls, and continuous improvement projects.

Global logistics planning spans Europe, Asia, the Middle East, and the Americas

- Collaborated with project managers to direct logistics for a $16M cargo screen project in Saudi Arabia.
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- Achieved an average of 10% savings by negotiating domestic and international shipping rates for a startup company.
- Managed shipment of over 300 CT X-ray systems domestically and internationally.

Education & Credentials

BS, Supply Chain Management (in progress) – NORTHEASTERN UNIVERSITY,
Certified in Transportation & Physical Distribution Management

Expertise includes: •Export Compliance •Imports• MRP Programs • Windows • MS Office • Access • PowerPoint •Security Systems • ISO 9000 • Regulatory

Professional Overview

Sr. Logistics Manager/Associate Logistics Manager — MOBIUS IMAGING/STRYKER: 2014-Present

- Built and established the logistics department. Obtained official product classification with the US Department of Commerce.
- Handled all import and exports related needs.
- Work with materials department, supplier shipping terms, contracts, and reviewed company insurance policy.
- Work with Trade Compliance, and Regulatory. collaborate with Enterprise Planning and Logistics Operations.
- Managed the shipping and receiving and transfer of inventory
- Acting Facilities Manager, built out a new manufacturing facility and multiple expansions.
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- Acted Company IT, tasked with establishing a legitimate server and phone system to accommodate growth.
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Logistics and Distribution Manager — VIKING SYSTEMS, CONMED CORP: (2011-2014)

- Improved the logistics department and distribution network; modified procedures.
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Other: **Import/Export Compliance Coordinator**, FLIR SYSTEMS: Performed contract review, maintained license tracking through government agencies, and prepared submittals for state and commerce departments.
Veteran US NAVY.

Preferred Name
Akshay Shetty
Aladin Milutinovic
Alysson Bean
Amanda Odoom
Anthony Simonenko
Austen McDonough
Barbara Bell
Bounemy Chanthavong
Brett Morehouse
Brian Leger
Chivy Ros
Chris Thurrott
Colin Travers
Colleen MacKenzie
Dan Quinn
Daniel Doucette
Daniel Heath
Danika Loeum
David Roxo
Doran Dibble
Doug Swaffer
Douglas Clowes
Ebangha Tanyi
Elizabeth Jewett
Francisco Brasil
Grant Stevens

Gunther Becht
Hamid Naseri
Huy Phan
Isaac Boasiako
Jaime Lawler
Jakob Stevenson
James Skehan
Jayme Giancola
Jeffrey Wood
Jenna Light
Joel Monaco
John Betzner
John Ghazey
John Marrazzo
John Wooldridge
Johnathan Thompson
Jonathan Birse
Jonathan Yuen
Katie Swanson
Kelsey Jewett
Ken Hilts
Kevin Provencher
Kevin Wilcox
Kyle Schwartz
Leigha Rego
Leon Thang
Lisandro Embon

Maritza Castillo
Mark Amirault
Maura Driscoll
Michael Boucher
Michael Campbell
Michael Connor
Michael Napolitano
Michael O'Keeffe
Mike Allen
Naaila Phoenix
Nami Reddy
Nathan Penniman
Nicholas Deisadze
Nicole Heath
Patricia Blenk
Patrick Ryan
Paul Amarant
Ramanathan Raman
Randy Spencer
Richard Spencer
Rob Michaud
Rob Powell
Robert Alper
Robert Kwiatkowski
Roopa Guttal
Ross Ricciuti
Russ Stanton

Ryen Bailey
Saad Syed
Scott Magovern
Seng Bouphavongsa
Seth Deane
Sheraz Tariq
Sophalla Khun
SOUHEIL BENZERROUK
Stephanie Doyle
Steve White
Suwen Ma
TED ASKAR
Ted Daley
Thomas Burgess
Timothy Lanoue
tom mccole
William O'Herren
William Theriault
Yuriy Lusakhpuryan

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

OR

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

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

4H

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: Stryker Corporation

Physical Address: 1941 Stryker Way

City: Portage State: MI Zip: 49002

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 269-501-7850 Website: www.stryker.com

Name of Designated Representative (DR): Joseph Glaspie

Licensing Company Email: statelicensing1@stryker.com DR Email: joe.glaspie@stryker.com

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

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

Name: Not Applicable-no pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: MI

Parent Company (if any): N/A

Corporation Name: Stryker Corporation

Mailing Address: 1941 Stryker Way

City: Portage State: MI Zip: 49002

Telephone: 269-501-7850 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979	SEC Registration Number: 001-13149	Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

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

Stryker Corporation

Facility Name

Joseph Glaspie

Print Name of Authorized Person Submitting Application

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

9 April 2024

Date

Board Use Only	Date Received: 6/4/24	Amount: $1000-CK 126888

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
STRYKER INSTRUMENTS
4100 EAST MILHAM AVE.
KALAMAZOO, MI 49001
Registration Number: 1811755
FEI Number*: 1811755
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Kim Wiersema
Stryker Instruments
1941 Stryker Way
Portage, MI 49002
Phone: 269-8001381

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

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Page Last Updated: 05/20/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

STRYKER CORPORATION

was validly incorporated on February 20 , 1946 as a Michigan DOMESTIC PROFIT CORPORATION, and said corporation is validly in existence under the laws of this state.

This certificate is issued pursuant to the provisions of 1972 PA 284 to attest to the fact that the corporation is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 1st day of May , 2024.

Linda Clegg

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24050010410

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

Stryker Corp.

Name	Role
Fletcher, Robert S.	Officer
Lobo, Kevin A.	Officer & Director
Menon, Viju S.	Officer
Pierce, J. Andrew	Officer
Stiles, Spencer S.	Officer

Name	Board of Directors
McCoy, Sherilyn	Director
Brainerd, Mary	Director
Caforio MD, Giovanni	Director
Datar PhD., Srikant	Director
Golston, Allan	Director
Silvernail, Andrew	Director
Skeete Tatum, Lisa	Director
Styker, Ronda	Director
Suri, Rajeec	Director

Name	List of Top 4 Shareholders & Percentages
The Vanguard	8.2%
Group BlackRock Inc	6.6%
John W. Brown	5.3%

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

5306007310APP22

STRYKER CORPORATION
1941 STRYKER WAY
PORTAGE, MI 49002

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

STRYKER CORPORATION
1941 STRYKER WAY
PORTAGE, MI 49002

LICENSE NO.
5306007310

EXPIRATION DATE
03/08/2025

23067140338

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

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

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

PRODUCER
Aon Risk Services Central, Inc.
MSC#17382
Aon
PO Box 1447
Lincolnshire IL 60069 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 FAX (A/C. No.): (800) 363-0105
E-MAIL ADDRESS:

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

INSURED
Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $100,000 Excluded $2,000,000 $3,000,000 $3,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY X Phys Dmge-Self Insd			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION						EACH OCCURRENCE AGGREGATE	
A A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		MWC31274324 AOS MWXS31274524 Excess WC - MI SIR applies per policy terms & conditions	02/01/2024 02/01/2024	11/01/2024 11/01/2024	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000

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

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570103677315

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Stryker Corporation MDEG License # (if applicable) N/A

Physical Address 1941 Stryker Way

City Portage State MI Zip 49002

Mailing Address (if different from physical address) Same as physical address

City _____ State _____ Zip _____

Telephone 269-501-7850 Website https://stryker.com

Licensing Company Email statelicensing1@stryker.com

Section 2: Personal Information

First Joseph Middle Allen Last Glaspie

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

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

Mailing Addre[redacted] Weathervane Trail

City Galesburg State MI Zip 49053

Telephone 269-501-7850 Email joe.glaspie@stryker.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Springport High School		09/91-05/95	
Address	**City**	**State**	**Zip**
300 West Main St.	Springport	MI	49284
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Central Michigan University		2006 - 2007	
Address	**City**	**State**	**Zip**
1200 S Franklin St	Mt Pleasant	MI	48859
Diploma/Degree obtained, if any			
MA Acquisitions Administration			

School Name		From - To (MM/YY – MM/YY)	
Ferris State University		1996 - 2000	
Address	**City**	**State**	**Zip**
1201 S State Street	Big Rapids	MI	49307
Diploma/Degree obtained, if any			
BS Plastics Engineering			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/17-Present	[redacted] Veathervane Trail	Galesburg	MI	49053
11/12-04/17	[redacted] Emerson	Dearborn	MI	48124
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Stryker Corporation			11/21-Present	
Business Address		**City**	**State**	**Zip**
1941 Stryker Way		Portage	MI	49002
Phone	**Title**		**Number of Employed Hours**	
269-501-7850	Sr Director Quality Assurance		5,200+	
Description of Duties				
See attached				

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

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

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

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

Continue on next page if additional space is needed.

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

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

This is in response to Question # _____. Provide all the following *where applicable*: Not Applicable

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6 MAY 2024
Date

I, Joseph Allen Glaspie, certify that as the MDEG Administrator for

Stryker Corporation,

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

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

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

Joseph Allen Glaspie
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

21 MAY 2024
Date

Board Use Only	Date Received: 6/4/24

1941 Stryker Way, Portage MI
Employee List - March 2023

First Name	Last Name	Worker Type	Employee Type
Christopher	Philipp	Employee	Regular
Stanley	Lepird	Employee	Regular
James	Walen	Employee	Regular
James	Sterner	Employee	Regular
Michael	Whitehead	Employee	Regular
Richard	Mitchell	Employee	Regular
Beverly	Joslin	Employee	Regular
Donell	Diamond	Employee	Regular
Scott	Lewis	Employee	Regular
Jon	Ahola	Employee	Regular
Gregory	Rabick	Employee	Regular
John	Lauria	Employee	Regular
Jennifer	Hoffman	Employee	Regular
Douglas	Staunton	Employee	Regular
Jennifer	Angel	Employee	Regular
Debra	Wood	Employee	Regular
Stephen	Reasoner	Employee	Regular
Megan	James	Employee	Regular
Matthew	Leclercq	Employee	Regular
Brian	Cripps	Employee	Regular
Jill	Rouse	Employee	Regular
Paul	Welch	Employee	Regular
Matthew	Powell	Employee	Regular
Holly	Smith	Employee	Regular
Philip	Marsh	Employee	Regular
Sara	Mack	Employee	Regular
Dylan	Crotty	Employee	Regular
Pedro	Muniz Medina	Employee	Regular
Spencer	Stiles	Employee	Regular
Christine	Unangst	Employee	Regular
Michael	Dozeman	Employee	Regular
Grant	Westphal	Employee	Regular
Heidi	Kovl	Employee	Regular
Ross	Thelen	Employee	Regular
Abigail	Kline	Employee	Regular
Carolyn	Ridderman	Employee	Regular
Brian	VanDerWoude	Employee	Regular
Trevor	Landon	Employee	Regular
David	Goodenough	Employee	Regular
Michael	Trumm	Employee	Regular
Michael	Kreutz	Employee	Regular
Stephanie	Brogan	Employee	Regular
Dannielle	Stap	Employee	Regular
Michael	Grotelueschen	Employee	Regular
Danielle	Tucker	Employee	Regular
Randall	Carpenter	Employee	Regular
Christopher	Brockman	Employee	Regular
Michael	Irvine	Employee	Regular
Leif	Nilsen	Employee	Regular
Gregory	Ciolek	Employee	Regular
Clark	Darrah	Employee	Regular
Todd	Wolf	Employee	Regular
Brey	Hansford	Employee	Regular

Michelle	Anderson	Employee	Regular
Naseeruddin	Syed	Employee	Regular
Rajesh	Konjeti	Employee	Regular
Patrick	Lafleche	Employee	Regular
Mary	Appelgren	Employee	Regular
Andrew	Perrin	Employee	Regular
Jessica	Spero	Employee	Regular
Adam	Bisnett	Employee	Regular
Cody	Goodpaster	Employee	Regular
Trevor	Land	Employee	Regular
Steven	Docsa	Employee	Regular
Edward	Kelley	Employee	Regular
Stephen	Isham	Employee	Regular
Sarah	Symko	Employee	Regular
Glen	Rocque	Employee	Regular
Julie	Winans	Employee	Regular
Jonathan	Hietbrink	Employee	Regular
Denise	Nelsen	Employee	Regular
Edward	Peterson	Employee	Regular
Alana	Kane	Employee	Regular
Krystal	Collins	Employee	Regular
Daniel	DeVries	Employee	Regular
Jacob	Foor	Employee	Regular
Elizabeth	Baker	Employee	Regular
William	Scott	Employee	Regular
John	Whitaker	Employee	Regular
Aaron	Morrow	Employee	Regular
Timothy	Kurtz	Employee	Regular
Donald	Verhoeven	Employee	Regular
Matthew	Ingle	Employee	Regular
Mark	Raabe	Employee	Regular
Julie	Brown	Employee	Regular
Kelly	Parrish	Employee	Regular
Brian	MacLachlan	Employee	Regular
Barbara	Sharpe	Employee	Regular
Ricky	Wilson	Employee	Regular
Dennis	Lacy	Employee	Regular
Robert	Baldwin	Employee	Regular
Kurt	Alphenaar	Employee	Regular
Matthew	Jousma	Employee	Regular
Susan	Sulka	Employee	Regular
Laura	MacLeod	Employee	Regular
Adam	Thelen	Employee	Regular
Keith	Behnke	Employee	Regular
Matthew	Owen	Employee	Regular
Jami	Sandt	Employee	Regular
Desiree	Campbell	Employee	Regular
Dan	Nummela	Employee	Regular
Jason	King	Employee	Regular
Sushmita	Bhushan	Employee	Regular
Paul	Franz	Employee	Regular
Brian	Schiedel	Employee	Regular
Gregory	Arens	Employee	Regular
Kristi	Brunner	Employee	Regular
Ali	Moaiery	Employee	Regular

Gary	Kalinka	Employee	Regular
Brian	Crum	Employee	Regular
WiSeon	Salisbury	Employee	Regular
Kristin	Colby	Employee	Regular
Stella	Radeva	Employee	Regular
Jayme	Carhart	Employee	Regular
Brian	Smith	Employee	Regular
Muzafar	Sayeeduddin	Employee	Regular
Nathan	Hogan	Employee	Regular
Jeffery	Scott	Employee	Regular
Juan	Santos	Employee	Regular
Casey	Metzger	Employee	Regular
Kelly	Davis	Employee	Regular
Philip	Woods	Employee	Regular
Amanda	Ryan	Employee	Regular
Joseph	Welch	Employee	Regular
Jason	Wroblewski	Employee	Regular
Dennis	Meyer	Employee	Regular
Kasey	Dinzik	Employee	Regular
Amy	Rozeboom	Employee	Regular
Andrew	Bentz	Employee	Regular
Minkah	Curtis	Employee	Regular
Zachary	Harris	Employee	Regular
James	Ford	Employee	Regular
Thomas	Newport	Employee	Regular
Craig	Volstromer	Employee	Regular
Sheila	Allen	Employee	Regular
James	Beachnau	Employee	Regular
Mathew	Rembowicz	Employee	Regular
Gary	Brown	Employee	Regular
Keith	Knag	Employee	Regular
Adam	Downey	Employee	Regular
Matthew	Brougham	Employee	Regular
Robin	Babaris	Employee	Regular
Jason	Holroyd	Employee	Regular
Bryan	Mohney	Employee	Regular
Torre	Goodman	Employee	Regular
Stephanie	Agnew	Employee	Regular
Jeremy	Vryhof	Employee	Regular
Parikshit	Atre	Employee	Regular
David	Lamorandier	Employee	Regular
Michael	Laubenthal	Employee	Regular
Allyson	Schouwburg	Employee	Regular
Katie	Surprenant	Employee	Regular
Lisa	Schreiner	Employee	Regular
Jonathan	Reggio	Employee	Regular
Christina	McKee	Employee	Regular
Carla	Fish	Employee	Regular
Kyle	Klumpp	Employee	Regular
Daniel	Martinson	Employee	Regular
Gregory	Gohl	Employee	Regular
Gabriel	Harshman	Employee	Regular
David	Quaid	Employee	Regular
Brian	Franck	Employee	Regular
Dillon	Olmstead	Employee	Regular

Jason	Force	Employee	Regular
Vicki	Block	Employee	Regular
James	Fitzgerald	Employee	Regular
Rick	Boyer	Employee	Regular
Gerard	Mouatt	Employee	Regular
Darren	Zielonka	Employee	Regular
Daniel	Davie	Employee	Regular
Andrew	Esper	Employee	Regular
Michelle	Peterson	Employee	Regular
Brittany	Zoeller	Employee	Regular
Charles	McKissic	Employee	Regular
Tanya	Nowak	Employee	Regular
Rachel	VanderGenugten	Employee	Regular
Andrea	Houseman	Employee	Regular
Douglas	Hines	Employee	Regular
Justin	Andrews	Employee	Regular
Erik	Berg	Employee	Regular
Yoshiro	Yamamoto	Employee	Regular
Robert	Rogalski	Employee	Regular
Whitney	Aitken	Employee	Regular
Karolyn	Westmoreland	Employee	Regular
Michael	Weslosky	Employee	Regular
Nathaniel	Osborn	Employee	Regular
James	Kendzior	Employee	Regular
Michael	Filary	Employee	Regular
Lindsay	Harris	Employee	Regular
Nicholas	Miller	Employee	Regular
Ian	Walsh	Employee	Regular
Stephani	Herbert	Employee	Regular
Jun	Ge	Employee	Regular
James	Koprolces	Employee	Regular
Conor	Mac an Tuile	Employee	Expatriate
Michael	Hossack	Employee	Regular
Megan	Strong	Employee	Regular
Thomas	Sprinkle	Employee	Regular
Vijaykaartik	Kumar	Employee	Regular
Art	Rush	Employee	Regular
David	Boboltz	Employee	Regular
Anthony	Noora	Employee	Regular
Missty	Black	Employee	Regular
Angela	Andress	Employee	Regular
Jeffrey	Kaiser	Employee	Regular
Beau	Kidman	Employee	Regular
Christina	McClure	Employee	Regular
Karen	McPhail	Employee	Regular
Tyrus	Lyle	Employee	Regular
Travis	Thorpe	Employee	Regular
Maranda	VanBruaene	Employee	Regular
Steven	Garber	Employee	Regular
Ronald	Smith	Employee	Regular
Laurie	Herl	Employee	Regular
Timothy	Maldag	Employee	Regular
Stephanie	Copeman	Employee	Regular
Brandon	McKoy	Employee	Regular
Walter	Celenski	Employee	Regular

Scott	Bauer	Employee	Regular
Mathew	Bresson	Employee	Regular
Alva	Jauregui	Employee	Regular
Nancy	James	Employee	Regular
Lauren	Boven	Employee	Regular
Bradley	Kuiper	Employee	Regular
Kevin	VanDyk	Employee	Regular
Scott	Lawrence	Employee	Regular
Daniel	Cook	Employee	Regular
Steven	Rolfsen	Employee	Regular
George	Krenk	Employee	Regular
Hannah	Elmblad	Employee	Regular
Kasey	Harden	Employee	Regular
Chad	Perry	Employee	Regular
Tirup	Patel	Employee	Regular
Stacie	Ferschweiler	Employee	Regular
Robert	Enquist	Employee	Regular
Megan	Finley	Employee	Regular
James	Flatt	Employee	Regular
Ronald	DeVoe	Employee	Regular
Katherine	Longman	Employee	Regular
Michael	Zollinger	Employee	Regular
Janet	Thelen	Employee	Regular
Lydia	Roth	Employee	Regular
Ian	Hesketh	Employee	Regular
Nicole	Moore	Employee	Regular
Lisa	Holmes	Employee	Regular
Matthew	Pastrick	Employee	Regular
Scott	Blackwell	Employee	Regular
Skylar	Clark	Employee	Regular
Geoffrey	Ehlers	Employee	Regular
Hillary	Davis	Employee	Regular
Cory	Welch	Employee	Regular
Tom	Hemingway	Employee	Regular
Dawn	Pearson	Employee	Regular
Katherine	Shuler	Employee	Regular
Brett	Merkel	Employee	Regular
Christopher	Noonan	Employee	Regular
Zachary	Grau	Employee	Regular
Cassandra	Riske	Employee	Regular
Craig	Davis	Employee	Regular
Kevin	Lewis	Employee	Regular
Amanda	Ferraro	Employee	Regular
Samuel	Bossley	Employee	Regular
Brian	Bergsma	Employee	Regular
Kyle	Batzer	Employee	Regular
Joshua	Fagan	Employee	Regular
Robert	Dodde	Employee	Regular
Michele	Kennedy	Employee	Regular
Jessica	Ward	Employee	Regular
David	Stevens	Employee	Regular
Jill	Hunt	Employee	Regular
Brandon	Jominy	Employee	Regular
Steven	Mullins	Employee	Regular
Jesse	Vanabel	Employee	Regular

Christopher	Fulling	Employee	Regular
Michael	Buss	Employee	Regular
Sarah	Newcomer	Employee	Regular
Andrea	Westphal	Employee	Regular
Benjamin	Fineout	Employee	Regular
Nicholas	Post	Employee	Regular
Tyler	Flynn	Employee	Regular
Angela	Billmeyer	Employee	Regular
Stephen	Green	Employee	Regular
Matthew	Hanley	Employee	Regular
Daniel	Dalenberg	Employee	Regular
Kurtis	Fraaza	Employee	Regular
Xiaoping	Li	Employee	Regular
Brian	Connolly	Employee	Regular
Susanne	Galin	Employee	Regular
Mary	Mauro	Employee	Regular
Laura	Rand	Employee	Regular
Ana	Baker	Employee	Regular
Erin	Bissonnette	Employee	Regular
Gregory	McEwan	Employee	Regular
Alexander	Kingma	Employee	Regular
Kyle	VondenBenken	Employee	Regular
Clint	Olsen	Employee	Regular
Ross	Nave	Employee	Regular
Ryan	Walters	Employee	Regular
Hannah	Romzek	Employee	Regular
Jennifer	Baker	Employee	Regular
Brian	Sidow	Employee	Regular
Adam	Simon	Employee	Regular
Andrew	Klumpp	Employee	Regular
Loran	Paprocki	Employee	Regular
Eric	MacKenzie	Employee	Regular
Benjamin	VanDyken	Employee	Regular
Christopher	Jones	Employee	Regular
Trevor	Lambert	Employee	Regular
Kimberly	Wiersema	Employee	Regular
Jun	Guo	Employee	Regular
Shawna	Clauser	Employee	Regular
Jordon	Lively	Employee	Regular
Janani	Gopalkrishnan	Employee	Regular
Jacob	Livingston	Employee	Regular
Stefan	King	Employee	Regular
Shannon	Hunt	Employee	Regular
Kelli	Dykstra	Employee	Regular
Byron	Izenbaard	Employee	Regular
Mary	Schwartz	Employee	Regular
Brad	Garrod	Employee	Regular
Shane	Muller	Employee	Regular
Brent	Fredryk	Employee	Regular
Owen	Blough	Employee	Regular
Jennifer	Brice	Employee	Regular
Austin	Brancheau	Employee	Regular
Kathryn	Herweg	Employee	Regular
Spencer	Wiard	Employee	Regular
Kevin	Schipper	Employee	Regular

James	Pencek	Employee	Regular
Joe	Keithley	Employee	Regular
Joshua	Colvin	Employee	Regular
Andrew	Kohtala	Employee	Regular
Zachary	Bolthouse	Employee	Regular
Emily	Gross	Employee	Regular
Keven	Chambers	Employee	Regular
Kyle	Hanis	Employee	Regular
Tyler	Selk	Employee	Regular
Arun	Rao	Employee	Regular
Kelly	Stalford	Employee	Regular
Dean	Rigoni	Employee	Regular
Michael	Pearison	Employee	Regular
David	Colao	Employee	Regular
Caitlyn	Covault	Employee	Regular
Sarah	Kulow	Employee	Regular
Thomas	Stilson	Employee	Regular
Ryan	Savard	Employee	Regular
Amy	Stump	Employee	Regular
Jordan	Baratono	Employee	Regular
Michel	Bower	Employee	Regular
Jason	Faulconer	Employee	Regular
Daniel	Villanueva	Employee	Regular
Laurence	Zemlick	Employee	Regular
Sarah	Edinger	Employee	Regular
Sarah	Husain	Employee	Regular
Rylee	Koole	Employee	Regular
Aline	Thielking	Employee	Regular
Mallory	Quinnell	Employee	Regular
Samuel	Rowan	Employee	Regular
Kristen	Spigiel	Employee	Regular
Kaitlyn	Lagoni	Employee	Regular
Sushmitha	Rajakutty	Employee	Regular
Faisal	Mahmood	Employee	Regular
James	Howarth	Employee	Regular
Whitney-Lexia	Potts	Employee	Regular
Andrew	Trail	Employee	Regular
Chiron	Herweg	Employee	Regular
Kevin	Packard	Employee	Regular
Joseph	Pellegrini	Employee	Regular
Galen	Bower	Employee	Regular
Steven	Walsh	Employee	Regular
Kevin	Kane	Employee	Regular
Jordan	Greegor	Employee	Regular
Mark	Novara	Employee	Regular
Rachael	Tafil	Employee	Regular
Daniel	Reichert	Employee	Regular
Stephanie	Keeler	Employee	Regular
Alisha	Eaton	Employee	Regular
Jerry	Adams	Employee	Regular
Rob	Niebauer	Employee	Regular
Nicholas	Toboy	Employee	Regular
Jeffrey	Timmer	Employee	Regular
Francis	Bell	Employee	Regular
Zachary	Marvin	Employee	Regular

Andrea	Pluta	Employee	Regular
Alexander	Kolenko	Employee	Regular
Valerie	Bloomer	Employee	Regular
Ivan	Gallegos	Employee	Regular
Brian	Bodamer	Employee	Regular
Sylvia	Page	Employee	Regular
Alex	Dietrich	Employee	Regular
Andrea	Wallen-Gerding	Employee	Regular
Eric	Yonkers	Employee	Regular
Marc	Stein	Employee	Regular
Natalie	Comparoni	Employee	Regular
Ryan	Miller	Employee	Regular
Shane	Rueffer	Employee	Regular
Zachary	Westdorp	Employee	Regular
Vanessa	West	Employee	Regular
Mohamad	El Atwani	Employee	Regular
Kristina	Eaton	Employee	Regular
Tami	Snell	Employee	Regular
Kelsey	Gerlofs	Employee	Regular
Hans	Geiger	Employee	Regular
Keith	Nearpass	Employee	Regular
Camille	Haburne	Employee	Regular
Ross	Tashjian	Employee	Regular
Aimee	Griffin	Employee	Regular
William	Breznau	Employee	Regular
David	Allan	Employee	Regular
Marc	Arthur	Employee	Regular
Jeffrey	Kirschensteiner	Employee	Regular
Sara	Wiseman	Employee	Regular
Keith	Van Liere	Employee	Regular
David	Jeng	Employee	Regular
Matthew	Layman	Employee	Regular
Nicole	Ritter	Employee	Regular
Heather	Graham	Employee	Regular
Robert	Moore	Employee	Regular
Anna	Sinclair	Employee	Regular
Gwynneth	St. John	Employee	Regular
Burton	Judson	Employee	Regular
Prudence	Boy	Employee	Regular
Kristen	Hicks	Employee	Regular
Hanna	Kasper	Employee	Regular
Jeremy	Carr	Employee	Regular
Tia	James	Employee	Regular
Dena	Rennaker	Employee	Regular
Michele	Britton	Employee	Regular
Jennifer	Baker	Employee	Regular
Terri	Bong	Employee	Regular
Eduardo	Ramirez Martinez	Employee	Regular
David	Maile	Employee	Regular
Josephine	Campbell	Employee	Regular
Krishnamurthy	Belagali	Employee	Regular
Caitlyn	McGrail	Employee	Regular
Emily	Warren	Employee	Regular
Amanda	Martin	Employee	Regular
Douglas	Wolf	Employee	Regular

Amanda	Hughes	Employee	Regular
Jenna	Coyle	Employee	Regular
Sara	Gomaa	Employee	Regular
Amanda	Townsend	Employee	Regular
Sherry	Sourial	Employee	Regular
Dale	Pease	Employee	Regular
Emily	Williamson	Employee	Regular
Eric	Girou	Employee	Regular
Nathan	Rocker	Employee	Regular
Tiffany	Powell	Employee	Regular
Anna	Foley	Employee	Regular
Andrew	Mallery	Employee	Regular
Zachary	Jarman	Employee	Regular
Donald	Beebe	Employee	Regular
Tabatha	Olmstead	Employee	Regular
Dina	Leone	Employee	Regular
Angela	Kelly-Sanford	Employee	Regular
Dustin	Payne	Employee	Regular
Christine	Krieger	Employee	Regular
Gian Carlo	Alpuche	Employee	Regular
Marisa	Witcpalek	Employee	Regular
Brendan	Schneider	Employee	Regular
John	Noble	Employee	Regular
Patrick	Hooper	Employee	Regular
Noah	Needler	Employee	Regular
Rex	Eaton	Employee	Regular
Jeanna	Malkemes	Employee	Regular
Jody	Pennock	Employee	Regular
Kody	Carpenter	Employee	Regular
Ryan	Bowman	Employee	Regular
Sara	Barron	Employee	Regular
Jason	Lam	Employee	Regular
Austin	Borton	Employee	Regular
Jonathan	Boyer	Employee	Regular
Sinan	Mandwee	Employee	Regular
Lucas	Gsellman	Employee	Regular
Allyson	Maurer	Employee	Regular
Kimberly	Sullivan	Employee	Regular
Jillian	Freudenburg	Employee	Regular
Zachary	Rapson	Employee	Regular
Wales	Christian	Employee	Regular
Omar	Villalon-Mora	Employee	Regular
Ashley	McCarty	Employee	Regular
Lam	To	Employee	Regular
Alyssa	Rendon	Employee	Regular
Brooke	Mason	Employee	Regular
Simi	Kothanath	Employee	Regular
James	Novorita	Employee	Regular
Colette	Chung	Employee	Regular
Dennis	Regan	Employee	Regular
Beth	Anderson	Employee	Regular
Sunil Udaya Simha	Moda	Employee	Regular
Rahul	Eapen	Employee	Regular
Garry	Back	Employee	Regular
Jason	Beach	Employee	Regular

Nadia	Sunny	Employee	Regular
Steven	Bandos	Employee	Regular
Blessen	Joseph	Employee	Regular
Erick	Muniz	Employee	Regular
Connor	Murphy	Employee	Regular
Gena	Reist	Contingent	
Olivia	Stewart	Employee	Regular
Carlyne	Schilling	Employee	Regular
Jena	Nielsen	Employee	Regular
Colleen	Fahling	Employee	Regular
Tarun	Giridhar	Employee	Regular
Ryan	Fieldbinder	Employee	Regular
Fransua	Muniz Valentin	Employee	Regular
Jacob	Betzold	Employee	Regular
Jason	Cassar	Employee	Regular
Alexandra	Diskerud	Employee	Regular
Alex	Wegner	Contingent	
Allison	Bolthouse	Employee	Regular
Nils	Miron	Employee	Regular
Christopher	Dickson	Employee	Regular
William	Burek	Employee	Regular
Angeliki	Kasi	Employee	Regular
Ashley	Smith	Employee	Regular
Joseph	Giordano	Employee	Regular
SCOTT	HELMBOLD	Employee	Regular
Arianna	Krenk	Contingent	
Alexander	Wright	Employee	Regular
CHRISTINA	COOPER	Employee	Regular
Clayton	Mandigo	Employee	Regular
Kendra	Pilon	Employee	Regular
Robert	Karas	Employee	Regular
Martha	Harding	Employee	Regular
BRENT	RAKLOVITS	Employee	Regular
Adam	Timm	Employee	Regular
Kaile	Johnson	Employee	Regular
Wyatt	Kowall	Employee	Regular
Robert	Berrington	Employee	Regular
Kaleb	Munro	Employee	Regular
Wendy	Brummel	Employee	Regular
Steven	Burkhardt	Employee	Regular
Taylor	Shine	Employee	Regular
Kaitlyn	Neihouser	Employee	Regular
Marin	DesNoyer	Employee	Regular
Kaycee	Eichinger	Employee	Regular
Bansili	Desai	Employee	Regular
Jordan	Anderson	Employee	Regular
Brianne	Thomas	Employee	Regular
Jacob	Stephens	Employee	Regular
Paul	Teini	Employee	Regular
Jeffrey	Jacobs	Employee	Regular
Hunter	Hoogakker	Employee	Regular
Hannah	Asher	Employee	Regular
Steven	Krentz	Employee	Regular
Brandon	O'Neill	Employee	Regular
Tracey	Sutterfield	Employee	Regular

Amy	French	Employee	Regular
Kyle	Prins	Employee	Regular
James	Pabis	Employee	Regular
Josh	Kidder	Employee	Regular
Todd	Howe	Employee	Regular
Lindsey	Luginbill	Employee	Regular
Blake	Weimer	Employee	Regular
Matthew	Veldheer	Employee	Regular
Clayton	Armfield	Employee	Regular
Allisa	Troutman	Employee	Regular
Harsh	Sinha	Employee	Regular
Stacy	Belanger	Employee	Regular
Kristin	Dillon	Employee	Regular
William	Tierney	Employee	Regular
Meredith	Waldron	Employee	Regular
James	Dunlop	Employee	Regular
Tiffany	Ritter	Employee	Regular
Bryan	Hann	Employee	Regular
Eneas	Kane	Employee	Regular
Weiyi	Ding	Employee	Regular
Adam	Lee	Employee	Regular
Ryan	Metcalf	Employee	Regular
David	Pearson	Employee	Regular
Phillip	Lindeman	Employee	Regular
Sameer	Singh	Employee	Regular
Nicolas	Wainwright	Employee	Regular
Janelys	Martin	Employee	Regular
Jordan	Mazurek	Employee	Regular
Brittni	Thomson	Employee	Regular
Steven	Kaplan	Employee	Regular
Connor	McCarthy	Employee	Regular
Mohammad	Usman	Employee	Regular
Janna	O'Halloran	Employee	Regular
Phillip	Michaelson	Employee	Regular
Betty	Medina	Employee	Regular
Jordan	Lada	Employee	Regular
Whitney	Cullen	Employee	Regular
Brandi	Inglett	Employee	Regular
Elizabeth	Rosso	Employee	Regular
Ted	Wilson	Contingent	
Rebecca	Pipkorn	Employee	Regular
William	Schmidt	Employee	Regular
Nicholas	Cekola	Employee	Regular
Daniel	Osterhart	Employee	Regular
Gilbert	Cross	Employee	Regular
Marc	Carls	Contingent	
Chase	Philport	Employee	Intern
Heather	Steele	Employee	Regular
Sarah	Sokolski	Employee	Regular
Jared	Heersema	Employee	Regular
David	Gipe	Employee	Regular
Hillary	Eley	Employee	Regular
Daniel	Mermuys	Employee	Regular
Jordan	Stiverson	Employee	Regular
Mary	Kovacic	Employee	Regular

Stephen	Ward	Employee	Regular
Taylor	Teague	Employee	Regular
Matthew	Grimm	Employee	Regular
Cameron	Hartman	Employee	Regular
Justin	Hallead	Employee	Regular
Kristine	Losiewski	Employee	Regular
Joanna	French	Employee	Regular
Arthur	Pallar da Silva	Employee	Regular
Brianna	LaBelle-Hahn	Employee	Regular
Erik	Donarski	Employee	Regular
Aaron	LaBomascus	Employee	Regular
Tore	Franzen	Employee	Regular
Denise	Lubitz	Contingent	
Jonathon	Warren	Employee	Regular
Lisa	Kamischke	Employee	Regular
Shripad	Dhoopagunta	Employee	Regular
John	Snodgrass	Employee	Regular
James	Chapman	Employee	Regular
Jamie	Bos	Employee	Regular
Deborah	Reinbold	Employee	Regular
Micah	Klaassen	Employee	Regular
Bradley	Allen	Employee	Regular
Melissa	Grant	Employee	Regular
Cathy	Leach	Employee	Regular
Andrew	Reynolds	Employee	Regular
Stephanie	Kennedy	Employee	Regular
Chris	Talbott	Employee	Regular
Giuseppe	Cracolici	Employee	Regular
Shanmugasundaram	Aruchamy	Employee	Regular
Karli	Davis	Employee	Regular
Ryan	Avery	Employee	Regular
Camille	Mercier	Employee	Regular
Frank	Pighetti	Employee	Regular
Bethany	Balash	Employee	Regular
Olivia	Norman	Employee	Regular
Nathaniel	Mishler	Employee	Regular
Kristin	Sturdy	Employee	Regular
Jessica	Kelley	Employee	Regular
Hannah	Poisson	Employee	Regular
Sarah	Watson	Employee	Regular
Natasha	Baig	Employee	Regular
Tyler	Rendon	Employee	Regular
Christopher	Keizer	Employee	Regular
Peter	Bensel	Employee	Regular
JOERG	Warmuth	Employee	Regular
Amy	Rokos	Employee	Regular
Tara	Gish	Employee	Regular
Benita	Devadas	Employee	Regular
Isayha	Davis	Employee	Regular
Alyssa	Viness	Employee	Regular
Kyle	Cryderman	Employee	Regular
JOHN	SEARS	Employee	Regular
Erik	Reber	Employee	Regular
ROBERT	VELLA	Employee	Regular
Randy	Schafer	Employee	Regular

Alex	Vincentini	Employee	Regular
Rakesh	Gundu	Employee	Regular
Denise	Azcui	Employee	Regular
Elizabeth	Murray	Employee	Regular
Courtney	Wiegand	Employee	Regular
Nicholas	Fenton	Employee	Regular
Amanda	Ferrante	Employee	Regular
Natalie	McQuade	Employee	Regular
Savannah	Crooks	Employee	Regular
Tyler	Henniges	Employee	Regular
Cassandra	Ingram	Employee	Regular
Emma	Shimek	Employee	Regular
Hamilton	Mutschler	Employee	Regular
Francesca	Pizzini	Contingent	
Brian	Jacoby	Employee	Regular
Anna	Lee	Employee	Regular
Brent	Smith	Employee	Regular
RYAN	KRULL	Employee	Regular
ANU	JINDAL	Employee	Regular
Neal	Malackowski	Employee	Regular
Andrew	Garland	Employee	Regular
Daniel	McGrail	Employee	Regular
Kevin	Eschen	Employee	Regular
MATTHEW	WOLFE	Employee	Regular
Amelia	Richardson	Employee	Regular
Kevin	Mattison	Employee	Regular
Alison	Renkiewicz	Employee	Regular
Dominique	McDuffey	Employee	Regular
Stephanie	Mandigo	Employee	Regular
Derek	Lewis	Employee	Regular
Saurabhi	Sawant	Contingent	
Hillary	Price	Contingent	
Emma	Neuendorff	Employee	Regular
Robert	Carr	Employee	Regular
Clayton	Meyers	Employee	Regular
Grant	Nagrant	Employee	Regular
Levon	Cimonian	Employee	Regular
Ty	McNall	Employee	Regular
HARRISON	WALKER	Employee	Regular
Dennis	Thomas	Employee	Regular
Aileen	Francis	Employee	Regular
Reid	Czepcinski	Employee	Regular
Mackenzie	Byler	Employee	Regular
Michael	Drobny	Employee	Regular
Randal	Flowers	Employee	Regular
Carrie	Dearing	Employee	Regular
Logan	Wright	Employee	Regular
Sarah	Yaqub	Employee	Regular
Brooke	Sidwell	Employee	Regular
Anne	Crawford	Contingent	
Abigail	Fair	Employee	Regular
Shivangi	Mukati	Contingent	
Emily	Willis	Employee	Regular
Mitchell	Christian	Employee	Regular
Tyler	Howard	Contingent	

Rachel	Bosworth	Employee	Regular
Joseph	Bonadies	Employee	Regular
Christian	Pinter	Contingent	
Michael	Custer	Employee	Regular
Matthew	Schafer	Employee	Regular
Derek	Ingeson	Employee	Regular
Mason	House	Employee	Regular
Kevin	DeVries	Employee	Regular
Daniel	Huizenga	Employee	Regular
Karen	Peters	Employee	Regular
Levi	Leversee	Employee	Regular
Trevor	Ekin	Employee	Regular
Luke	Boulter	Employee	Regular
Robert	Novorita	Employee	Regular
BRADLEY	BELL	Employee	Regular
Dylan	Burkett	Employee	Regular
SAM	DARE	Employee	Regular
Brittany	Dunn	Employee	Regular
GRACE	WHITE	Employee	Regular
Michelle	Prince	Employee	Regular
Craig	Isser	Employee	Regular
Evan	Henry	Employee	Regular
Christopher	Dupree	Contingent	
Aisha	Lockett	Employee	Regular
Elisha	Krajcovic	Employee	Regular
Canyon	Duncan	Employee	Regular
Spencer	Jowkar	Employee	Regular
PATRICK	YOUNG	Employee	Regular
Stacy	Krauss	Employee	Regular
Nassma	Mandwee	Employee	Regular
Edward	Winter	Employee	Regular
Taylor	Pomeroy	Employee	Regular
Joseph	OReilly	Employee	Regular
Aryn	Tiller	Employee	Regular
Charles	Jiral	Employee	Regular
Nikhil	Patil	Employee	Regular
Preston	Fergon	Employee	Regular
Addison	Moore	Employee	Regular
ANGELA	ENOCHSON	Employee	Regular
Michael	Gumbko	Employee	Regular
Shahid Nawaz	Sanakhan	Employee	Regular
Spencer	VanSickle	Employee	Regular
HAILEY	UNDERWOOD	Employee	Regular
Michael	Perez	Employee	Regular
Luc	Esformes	Employee	Regular
Bailey	Flint	Employee	Regular
Idalice	Corkran	Employee	Regular
Taylor	Huie	Employee	Regular
Sean	Eagen	Employee	Regular
Anthony	Sieler	Employee	Regular
Jaron	Barnett	Employee	Regular
Harper	Calhoun	Contingent	
Malcolm	Macdonald	Employee	Regular
Richard	Batton	Employee	Regular
Kyle	Boughner	Employee	Regular

Meredith	Buchanan	Employee	Regular
Samantha	Richardson	Employee	Regular
Zachary	Markley	Employee	Regular
Chris	Stamatopoulos	Employee	Regular
Rachel	Schillmoeller	Employee	Regular
Grace	Trimpe	Employee	Regular
David	Merryman	Employee	Regular
Zachary	Pessia	Employee	Regular
Andrew	Stanger	Employee	Regular
Michael	Ford	Employee	Regular
Jessica	Curtis	Employee	Regular
Bradley	Ostergren	Employee	Regular
Benjamin	Cole	Employee	Regular
Leandra	Burke	Employee	Regular
Sage	Campbell	Employee	Regular
Matt	Hall	Employee	Regular
Robert	Esser	Employee	Regular
Christopher	Mikle	Employee	Regular
Shawn	Jones	Employee	Regular
Michael	Scoffin	Employee	Regular
William	Vogelgesang	Employee	Regular
Huma	Tabassum	Contingent	
Jessica	Esser	Employee	Regular
Kimberly	Wood	Employee	Regular
Rawley	Stanhope	Employee	Regular
Tania	Aguilar	Contingent	
Amy	Adams	Employee	Regular
Joseph	Glaspie	Employee	Regular
Simon	Chunkath	Employee	Regular
Juan	Reyes Gonzalez	Employee	Regular
Allen	Drost	Employee	Regular
Joseph	Trohimczyk	Contingent	
Bilal	Kaleem	Employee	Regular
Brianna	Forsthoefel	Employee	Regular
Jessica	Oakes	Employee	Regular
Robert	Robinson	Employee	Regular
James	Barrett	Contingent	
Bryce	Norwood	Employee	Regular
Slaven	Sutalo	Employee	Regular
Bridget	Chadwick	Employee	Regular
Satish	Kambhampati	Contingent	
Kathleen	McClellan	Employee	Regular
Iris	Townsend	Employee	Regular
Christopher	Theis	Employee	Regular
Helayna	Barrett	Contingent	
Michelle	Lula	Employee	Regular
Andrew	Feller	Employee	Regular
Anna	Oswalt	Employee	Regular
Caitlin	Carter	Employee	Regular
Baileigh	Clements	Employee	Regular
DAVID	WILLIAMS	Employee	Regular
Jade	Maile	Employee	Regular
Angie	O'Hara	Contingent	
Allison	Parks	Employee	Regular
Bryan	Lewis	Employee	Regular

Alexander	Anschutz	Employee	Regular
Ciera	Weiss	Employee	Regular
Alyssa	McCarthy	Employee	Regular
Bassam	Bitar	Employee	Regular
Amanda	Cowell	Employee	Regular
Stephanie	Blodgett	Employee	Regular
Joseph	Barth	Employee	Regular
Ryan	Rader	Employee	Regular
Ellis	Archuleta	Employee	Regular
Douglas	Heaney	Employee	Regular
Talha	Malik	Employee	Regular
Marianne	Preston	Employee	Regular
William	Smola	Employee	Regular
Sydney	Eger	Employee	Regular
MATTHEW	MORRISSEY	Employee	Regular
William	Stokes	Employee	Regular
Sai Sriramamurthy	Kollipara	Contingent	
Will	Chmelir	Contingent	
Abidemi	Ajayi	Contingent	
Scott	McBride	Employee	Regular
Mackenzie	McGough	Employee	Regular
Trevor	Montour	Employee	Regular
Holly	Roeder	Employee	Regular
Megan	Ingeson	Employee	Regular
Jasmine	Norwood	Employee	Regular
Adam	Mattus	Contingent	
Dhrumi	Shah	Contingent	
Mykel	Dolinski	Employee	Regular
Samuel	McClellan	Employee	Regular
Gabriel	Esseltine	Employee	Regular
Christopher	Stuart	Employee	Regular
Collin	Maker	Employee	Regular
Nicholas	Trevethan	Employee	Regular
Deryk	Atkins	Employee	Regular
Craig	Biehl	Employee	Regular
Cassandra	Chumley	Employee	Regular
Daniel	Krudy	Employee	Regular
Hannah	Chamberlin	Employee	Regular
Allyson	Loew	Employee	Regular
Cecelia	Attwell	Employee	Regular
Amanda	Oskoian-Wade	Employee	Regular
Phillip	VanOss	Employee	Regular
John	Miller	Contingent	
Ian	Dalrymple	Employee	Regular
Caitlin	Conway	Employee	Regular
Donna	Socha	Employee	Regular
Gunther	Maddock	Employee	Regular
Laura	Ginter	Employee	Regular
KAITLYN	BECKER	Employee	Regular
Kiaya	McFarland	Employee	Regular
Matthew	Kestner	Employee	Regular
Jeff	Hensler	Employee	Regular
August	Dunbar	Employee	Regular
Sarah	Stewart	Employee	Regular
Mark	Schmidt	Employee	Regular

Melanie	DeYoung	Employee	Regular
Kana	Moriyama	Employee	Regular
Brett	Kersh	Employee	Regular
Ciara	Hill	Employee	Regular
Michael	Preston	Employee	Regular
Keith	Chamberlain	Employee	Regular
Ashley	Petix	Employee	Regular
Megan	Utlak	Employee	Regular
Jaclyn	Schachtner	Employee	Regular
Lauren	Hartlieb	Employee	Regular
Bryan	Moore	Employee	Regular
Patrick	Roach	Employee	Regular
Frank	Zlomek	Employee	Regular
David	Kanniainen	Employee	Regular
Anissa	Rader	Employee	Regular
Dana	Paulson	Employee	Regular
Paul	Rummel	Employee	Regular
William	Coleman	Contingent	
Sydney	McDowell	Employee	Regular
Raoul	Fulgos	Contingent	
Mitchell	Galer	Employee	Regular
Griffin	Bruso	Employee	Regular
Estelle	Scharret	Employee	Regular
Jacob	Bastian	Employee	Regular
Dillan	Cerny	Employee	Regular
Justin	Henry	Employee	Regular
Erika	Muskus	Employee	Regular
Kyle	Oberlee	Employee	Regular
Jennifer	Ryan	Employee	Regular
Andrew	Buis	Employee	Regular
Valentina	Harding	Employee	Regular
Steven	Johnson	Employee	Regular
HERVIN	CRESPO-SANDOVAL	Employee	Regular
Taleah	Adams	Employee	Regular
Creighton	Bradley	Employee	Regular
Ryan	Spaulding	Employee	Regular
Zachary	Hansen	Employee	Regular
Kirsten	Scheller	Employee	Regular
Shannon	Cooper	Employee	Regular
Jonathan	Kelley	Contingent	
Spencer	Silvernail	Employee	Regular
Madeline	Watters	Employee	Regular
Imanii	Bush	Contingent	
Benjamin	Sturdevant	Contingent	
Venkata	Avula	Contingent	
Erika	Mallery	Employee	Regular
Leah	Thomas	Employee	Regular
Haley	Katenin	Employee	Regular
Adriana	Rotger	Employee	Regular
Alex	Wu	Employee	Regular
Avani	Sheth	Employee	Regular
Minakshi	Seth	Employee	Regular
Kyle	Johnson	Employee	Regular
Jay	Zmrhal	Employee	Regular
Kristie	Garza	Employee	Regular

Ben	Baldwin	Contingent	
Kyle	Herring	Employee	Regular
Daniel	Van Slooten	Employee	Regular
Katelyn	Arseneau	Employee	Regular
Leah	Nabors	Employee	Regular
Rachael	Selzer	Employee	Regular
Kayla	Kwolek	Employee	Regular
Justin	Novack	Employee	Regular
Laura	Boom	Employee	Regular
Maysara	Elazzazi	Employee	Regular
Analise	Avalos	Employee	Regular
Thomas	Hodgson	Employee	Regular
Julie	Clarke	Employee	Regular
Jordan	Jarosz	Employee	Regular
Megan	Noeske	Employee	Regular
Ericka	Lehnen	Employee	Regular
Diana	Ferreira	Contingent	
Noah	Boot	Employee	Regular
Stefanie	Hylarides	Employee	Regular
Dilara	Atkins	Employee	Regular
eugenio	duarte	Employee	Regular
Matthew	Smith	Employee	Regular
Daarina	Perry	Contingent	
Micheala	Tidwell	Contingent	
Jennifer	Campbell	Contingent	
Keyton	Barrone	Employee	Regular
Jeffrey	Haladik	Employee	Regular
Sean	Miller	Employee	Regular
Paul	Kratochwill	Employee	Regular
Adam	Justus	Contingent	
Erin	Rogers	Employee	Regular
Devon	Wilson	Contingent	
Rose	Nimmons	Contingent	
Arteasia	Davis	Contingent	
Katie	Randt	Contingent	
Rebecca	Stauch	Contingent	
Donovan	Reiley	Employee	Regular
Leah	Johnson	Contingent	
Suzannah	Schiefla	Contingent	
Robert	Suckow	Employee	Regular
SYDNEY	STOREY	Employee	Regular
Sarah	Struin	Contingent	
Ebony	Maynor	Contingent	

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

OR

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

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,848	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,189	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2018
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,108	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	$ 3,888	$ 2,841	$ 2,584	$ 2,223	$ 2,713
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	$ 3,673	$ 2,683	$ 2,281	$ 1,954	$ 2,562
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

Dollar amounts in millions except per share amounts or as otherwise specified.

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application – N/A

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Stryker Corporation

Pharmacy/Wholesaler License # (if applicable): not applicable

Physical Address: 1941 Stryker Way

City: Portage State: MI Zip: 49002

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

City: State: Zip:

Telephone: 269-501-7850 Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Joseph Middle: Allen Last: Glaspie

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

Date of Birth: 112/19/1976 SSN or ITIN: 386-04-5624 Sex: ■ M ☐ F ☐ X

Mailing Address: 9182 Weathervane Trail

City: Galesburg State: MI Zip: 49053

Telephone: 269-501-7850 Email: joe.glaspie@stryker.com

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

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

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? Not applicable		

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

School Name		From - To (MM/YY – MM/YY)	
Central Michigan University		2006-2007	
Address	**City**	**State**	**Zip**
1200 S Franklin St	Mt Pleasant	MI	48859
Diploma/Degree obtained, if any			
MS Acquisitions Administration			
School Name		From - To (MM/YY – MM/YY)	
Ferris State University		1996 - 2000	
Address	**City**	**State**	**Zip**
1201 S State St	Big Rapids	MI	49307
Diploma/Degree obtained, if any			
BS Plastics Engineering			
School Name		From - To (MM/YY – MM/YY)	
Springport High School		1991 - 1995	
Address	**City**	**State**	**Zip**
300 West Main St	Springport	MI	49284
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/2017 - Present	9182 Weathervane Trail	Galesburg	MI	49053
11/2012 - 4/2017	24434 Emerson	Dearboarn	MI	48124

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

Business Name			From - To (MM/YY – MM/YY)	
Stryker Corporation			11/2021 - present	
Business Address		**City**	**State**	**Zip**
1941 Stryker Way		Portage	MI	49002
Phone	**Title**		**Number of Employed Hours**	
269-501-7850	Sr Director Quality Assurance		5200+	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
SunMed Grand Rapids			1/2020 - 11/2021	
Business Address		**City**	**State**	**Zip**
2710 Northridge Dr NW		Grand Rapids	MI	49544
Phone	**Title**		**Number of Employed Hours**	
616-647-3430	Chief Operations Officer		3600+	
Description of Duties				
See attached resume				

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? Not applicable		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

22 MAY 2024
Date

I, Joseph Allen Glaspie, **certify that as the designated representative for**

Stryker Corporation,

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

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

Joseph Allen Glaspie
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

22 MAY 2024
Date

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

Joseph Allen Glaspie

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

22 MAY 2024

Date

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

State of MICHIGAN, ss. County of KALAMAZOO

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

Original Signature

22 MAY 2024

Date

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

Notary Public Signature

Elizabeth Murray
NOTARY PUBLIC - STATE OF MICHIGAN
Kalamazoo
My Commission Expires April 08, 2028
Acting in the County of Kalamazoo

(Seal)

JOSEPH GLASPIE

[redacted] Weathervane Trl. Galesburg, MI 49053 · [redacted]
Joseph.Glaspie@sbcglobal.net · linkedin.com/in/joe-glaspie-38b1761b

Results-driven and dedicated with wide-ranging experience in Quality and Operations leadership involving small to medium-sized manufacturing environments. Track record of devising, evaluating and implementing continuous process improvements to minimize waste and reduce cost while maximizing quality and yields.

EXPERIENCE

NOVEMBER 2021 – PRESENT

SR. DIRECTOR QUALITY ASSURANCE, STRYKER INSTRUMENTS

Lead a cross functional organization ensuring that Stryker Instrument's products are meeting our high quality standards.

- Collaborate with R&D and advanced operations to ensure quality deliverables are achieved through out the new product development process
- Develop post market strategies for dealing with customer complaints and adverse events associated with Stryker's products
- Ensure that all M&A integration strategies are in line with corporate requirements and that projects are in place to meet timelines
- Oversee and ensure that the shared service teams are properly resources to meet business needs; resources include product safety, microbiology, chemistry and metrology.

JAUARY 2020 – NOVEMBER 2021

CHIEF OPERATIONS OFFICER, SUNMED GRAND RAPIDS

Develop and execute both short-term and long-term strategies to meet company operational goals in production efficiency, quality, employee engagement, service and cost.

- Worked with the executive team to establish and deliver a company vision, mission and promise statement. Core values include Family, Respect, Accountability, Continuous Improvement and Adaptability
- Purchase and integration of two companies that drove revenue growth from $70M to $252M
- Implementation of Value Improvement Projects in 2020 that drove $4.1M in product cost change, identified $11M of product cost changes for 2021
- Implementation of ERP system for integrated companies that included updates to the order to cash and operations processes
- Worked with HR to implement company wide engagement survey and feedback process to set a baseline for improvement

SEPTEMBER 2019 – JANUARY 2020

SR. DIRECTOR OPERATIONS, STYKER MEDICAL PORTAGE

Director of Operations supporting $450 Million in COGS to produce hospital beds, stretchers, and emergency care products.

- Setting up a Continuous Improvement program to deliver over $3 Million in cost reductions through 2020
- Establishing a materials management organization and system to reduce waste by eliminating parts shortages

- Developing an engagement program to drive engagement actions identified from our annual engagement survey
- Driving yield improvements by daily management and fast response to manufacturing issues

APRIL 2017-SEPTEMBER 2019

DIRECTOR / SR. DIRECTOR QUALITY ASSURANCE, STRYKER AMERICAS

Regional leader consisting of 9 manufacturing facilities supporting 4 Stryker Business Units

- Partnership with Operations to drive improvements in throughput, cost, and compliance
- Delivered cost reductions to the business through inspection optimization
- Quality Management System Simplification
- Drove programs to deliver a reduction in product escapes and human error

OCTOBER 2015 – APRIL 2017

DIRECTOR OF OPERTIONS, STRYKER CHINA

Operations Leaders of a site with $20M COGS located in Suzhou, China

- Responsible for Safety, People, Quality, Service and Cost
- Drove cost reduction programs to remove 20% fixed cost
- Improved Operating Income and Cash Position to eliminate borrowing of cash and completely repaid corporate loans
- Collaborated with multiple partners to launch a low-cost power tool designed to serve emerging markets

NOVEMBER 2012 – OCTOBER 2015

DIRECTOR, QUALITY AND REGULATORY, STRYKER CHINA

- Developed validation strategy to reduce final inspection
- Collaboration with US Regulatory to implement China Label strategy
- Utilized lean process to reduce redundant activities within the manufacturing transfer process
- Collaboration with our Joint Replacements division to release product outside their QMS

OCTOBER 2008 – NOVEMBER 2012

MANAGER QUALIY ASSURANCE, STRYKER KALAMAZOO

- Implementation of Production Part Approval Process (PPAP)
- Owner of CAPA's tied to FDA remediation and part of Instruments QSIP program
- Developed purchasing controls procedure and supplier audit program
- Implemented incoming and in-process controls for the Instrument's Division
- Designed the Kalamazoo Quality Campus as part of Stryker's Global Quality and Operations initiative

MAY 2000 – OCTOBER 2008

MULTIPLE ROLES OPERATIONS / QUALITY, GENERAL MOTORS

- Advanced Supplier Quality Engineer – GMT 800 Interiors (Doors, Headliners, Consoles)
- Production Supervisor – Overseeing vehicle trim line supporting Safety, People, Quality, Service and Cost
- Assembly Plant Supplier Quality Manager – Management of daily issues that have an impact on the assembly center due to supplied components
- Launch Manager – Coordinate the activities related to the launch of a new vehicle into the Ramos Arizpe assembly center
- Manufacturing Manager – Leader of the vehicle trim department to drive improvements in Safety, People, Quality, Responsiveness and Cost. (5 Direct Reports – 320 Hourly Employees)

EDUCATION

MAY 2000
B.S. PLASTICS ENGINEERING, FERRIS STATE UNIVERSITY

2006-2007
M.S. ACQUISITIONS ADMINSTRATION, CENTRAL MICHIGAN UNIVERSITY
21 Credit Hours Completed

SKILLS

- Team Building and Training
- Lean Manufacturing
- Cost Reduction / Avoidance
- FDA 21CFR 820 / USP 51/52, 61/62
- Kaizen & 6s Events
- Statical Problem Solving (Red X)
- Regulatory Compliance
- Total Quality Management
- Policy / Procedure Development
- ISO 13485 Lead Auditor
- P&L Responsibilities & Expense Controls
- Change Management

41

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: Stryker Corporation

Physical Address: 6300 S. Sprinkle Rd

City: Portage State: MI Zip: 49002

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: _____ Website: www.stryker.com

Name of Designated Representative (DR): Richard Bassett

Licensing Company Email: statelicensing1@stryker.com DR Email: andy.bassett@stryker.com

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

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

Name: Not Applicable-no pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: MI

Parent Company (if any): N/A

Corporation Name: Stryker Corporation

Mailing Address: 6300 S. Sprinkle Rd

City: Portage State: MI Zip: 49002

Telephone: 214-287-4694 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

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

Stryker Corporation

Facility Name

Richard Bassett I

Print Name of Authorized Person Submitting Application

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

4-10-2024

Date

Board Use Only	Date Received: 6/10/24	Amount: $1000-Ck 12710

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing
New Search Back To Search Results

Establishment:
Stryker Medical Sprinkle Rd Facility
6300 S Sprinkle Rd
Portage, MI 49002
Registration Number: 3013127346
FEI Number*: 3013127346
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Divya Murali
Stryker
3800 E. Centre Ave
Portage, MI 49002
Phone: 1-269-5678254

Verified M.H 6/12/24

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

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm
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Page Last Updated: 05/20/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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Stryker Corp.	
Name	**Role**
Fletcher, Robert S.	Officer
Lobo, Kevin A.	Officer & Director
Menon, Viju S.	Officer
Pierce, J. Andrew	Officer
Stiles, Spencer S.	Officer
Name	**Board of Directors**
McCoy, Sherilyn	Director
Brainerd, Mary	Director
Caforio MD, Giovanni	Director
Datar PhD., Srikant	Director
Golston, Allan	Director
Silvernail, Andrew	Director
Skeete Tatum, Lisa	Director
Styker, Ronda	Director
Suri, Rajeec	Director
Name	**List of Top 4 Shareholders & Percentages**
The Vanguard	8.2%
Group BlackRock Inc	6.6%
John W. Brown	5.3%

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

STRYKER CORPORATION

was validly incorporated on February 20 , 1946 as a Michigan DOMESTIC PROFIT CORPORATION, and said corporation is validly in existence under the laws of this state.

This certificate is issued pursuant to the provisions of 1972 PA 284 to attest to the fact that the corporation is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 1st day of May , 2024.

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24050010410

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

5306007314APP22

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

STRYKER CORPORATION
6300 S SPRINKLE RD
PORTAGE, MI 49002

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

STRYKER CORPORATION
6300 S SPRINKLE RD
PORTAGE, MI 49002

LICENSE NO.
5306007314

EXPIRATION DATE
03/08/2025

23067150354

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

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

INSURED
Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	Y/N			AOS				
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A		MWXS31274524	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
	(Mandatory in NH)			Excess WC - MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

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

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570103677315

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Stryker Corporation — MDEG License # (if applicable): _____

Physical Address: 6300 S. Sprinkle Rd

City: Portage — State: MI — Zip: 49002

Mailing Address (if different from physical address): Same as physical address

City: _____ — State: _____ — Zip: _____

Telephone: 269-759-3664 — Website: https://stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Richard — Middle: Andrew — Last: Bassett I

Alias(es, nicknames, name changes, etc.): Not applicable

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

Mailing Addre[redacted]amaica Lane

City: Portage — State: MI — Zip: 49002

Telephone: 269-759-3664 — Email: andy.bassett@stryker.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Delton Kellogg High School		9/97-6/02	
Address	**City**	**State**	**Zip**
327 N Grove St	Delton	MI	49046
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Michigan Career Technical Institute		11/19/2003	
Address	**City**	**State**	**Zip**
11611 West Pine Lake Rd	Plainwell	MI	49080
Diploma/Degree obtained, if any			
GED			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/15-Present	[redacted] Jamaica Lane	Portage	MI	49002
From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/06 - 05/15	[redacted] Gull Prairie Dr apt 2b	Kalamazoo	MI	49048
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Stryker Corporation			11/09-Present	
Business Address		City	State	Zip
6300 S Sprinkle Rd		Portage	MI	49002
Phone	Title		Number of Employed Hours	
269-759-3664	Distribution Supervisor		29,000+	
Description of Duties				
See attached				

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

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

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

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

Continue on next page if additional space is needed.

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

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

This is in response to Question # _____. **Provide all the following *where applicable*:** **Not applicable**

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/3/2024
Date

I, Richard Andrew Bassett I, **certify that as the MDEG Administrator for**

Stryker Corporation,

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

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

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

Richard Andrew Bassett I
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/3/2024
Date

Board Use Only	Date Received: 6/10/24

[redacted]

Andy Bassett

Objective

- Obtain a challenging leadership position that applies creative problem solving and lean management skills to deliver a world-class experience to the customer.

Experience

Stryker
6300 S. Sprinkle Rd
Portage, MI 49002

Distribution Supervisor, Stryker Instruments • Sept 2022 – current

- Goal: guide and manage a diverse team to deliver on the goals of the business
- Oversee all distribution functions: shipping, receiving, inventory management, and repackaging
- Execute testing associated with SAP major releases.

Distribution Team Lead – Inbound, Stryker Instruments • March 2021 – Sept 2022

- Goal: Improve processes related to incoming shipments, drive down processing times to get materials to their final locations, and eliminate backlogged receipts.
- Support all functions related to inbound and internal processes: receiving, complaints, inventory management, inter/intracompany material transfers. Serve as the subject matter expert for nearly all SAP functions within 6300.
- Work closely with Customer Service to resolve RMA related discrepancies, Service team to facilitate transfers between locations, demand and planning teams to prioritize critical receipts, Accelerate team for SAP updates, RAQA regarding complaint returns, and SAP consultants for incident resolution.
- Established a partnership with Stryker Sustainability to take tourniquet cuffs that are not eligible for repackaging, saving the company over $100k per year at cost.

Distribution Supervisor, Stryker Craniomaxillofacial • April 2018 – March 2021

- Goal: Drive efficiencies and process improvements over a variety of warehouse functions following the SAP launch.
- Oversee all distribution functions: shipping, receiving, inventory management, open stock repackaging, and medical education.
- Execute testing associated with SAP major releases.
- Consistently deliver below budget for supplies, drive cost savings by utilizing a variety of vendors, and coordinate capital equipment purchases.
- Work closely with our 3PL partner in Indianapolis to resolve inventory and shipment issues, address complaints, and to improve the overall customer experience.
- Manage PPE supplies and distribution activities during the Covid-19 pandemic, ensuring our sales force was protected and well equipped to continue supporting our customers.

Marketing and Medical Education Supervisor, Stryker Instruments • July 2016 – March 2018

- Goal: Encourage fairness and flexibility in supporting business units with unique needs and requests to facilitate marketing and education events.
- Oversaw transition of the Navigation Med-Ed equipment from Flower Mound TX to Kalamazoo MI.
- Coordinated training and connected staff to local experts for Q&A and on-site support.
- 2017 statistics: 2191 events shipped, up over 10% from 2016. 74,000 items processed and 99.86% of events shipped on time.

Distribution Supervisor, Stryker Instruments • November 2009 – March 2018

- Goal: Guide a team of Material Handlers to put quality first, and to deliver on shipment goals as the business requires.
- Maintain stability and continuity among a team comprised primarily of temporary/short-term assignments.
- Monitor, track, and trend employee output: develop and coach individuals, including but not limited to those with performance issues, recognize individuals going above expectations.
- Analyze daily workload, prioritize as necessary, and utilize all available resources to cover any potential gaps.
- Ensure regulatory compliance particularly relating to Hazardous Materials and Dangerous Goods.
- Investigate and resolve equipment or systems (AS400) issues. Communicate resolution or necessary work-around as needed.
- Backfill Order Inventory Control role as necessary: act as a liaison between Customer Service and our 3PL partners to expedite deliveries, investigate and resolve complaints, and perform order maintenance.
  - During end-of-month, identify orders needed to reach Stryker's financial goals, monitor inventory levels for in-demand items and allocate them to orders for greatest financial impact, and communicate with SRs and RMs while searching for orders to ship.

Education

Delton Kellogg High School-Delton, Michigan June 2002

References available upon request

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Stryker Corporation

Pharmacy/Wholesaler License # (if applicable): not applicable

Physical Address: 6300 S Sprinkle Rd

City: Portage State: MI Zip: 49002

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

City: State: Zip:

Telephone: 269-759-3664 Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Richard Middle: Andrew Last: Bassett I

Alias(es, nicknames, name changes, etc.): Not applicable

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

Mailing Address: [redacted] Jamaica Lane

City: Portage State: MI Zip: 49002

Telephone: 269-759-3664 Email: andy.bassett@stryker.com

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

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

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? Not applicable		

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

School Name			From - To (MM/YY – MM/YY)
Michigan Career Technical Institute			11/19/2003
Address	City	State	Zip
11611 West Pine Lake Rd	Plainwell	MI	49080
Diploma/Degree obtained, if any			
GED			

School Name			From - To (MM/YY – MM/YY)
Delton Kellogg High School			9/1997 - 6/2002
Address	City	State	Zip
327 N Grove St	Delton	MI	49046
Diploma/Degree obtained, if any			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/15 - Present	[redacted]amaica Lane	Portage	MI	49002
4/2006 - 05/2015	[redacted]ull Prairie Dr Apt 2B	Kalamazoo	MI	49048
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

630 Sprinkle
Bassett

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

Business Name			From - To (MM/YY – MM/YY)	
Stryker Corporation			11/2009 - Present	
Business Address		**City**	**State**	**Zip**
6300 S Sprinkle Rd		Portage	MI	49002
Phone	**Title**		**Number of Employed Hours**	
269-759-3664	Distribution Supervisor		29,000+	
Description of Duties				
See attached resume				

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

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

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

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

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? **Not applicable**		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/23/2024
Date

630 Sprinkle
Bassett

I, Richard Andrew Bassett I, **certify that as the designated representative for**

Stryker Corporation,

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

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

Richard Andrew Bassett I
Print Name (First, Last)

R.B.
Original Signature (electronic, copies or stamps not accepted)

5/23/2024
Date

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

Richard Andrew Bassett I

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/22/2024

Date

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

State of Michigan, ss. County of Kalamazoo

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

Original Signature

5/22/2024

Date

Subscribed and Sworn to before me this 22 day of May 2024.

Donna Socha

Notary Public Signature

DONNA SOCHA
Notary Public - State of Michigan
County of Kalamazoo
My Commission Expires Mar 17, 2029
Acting in the County of Kalamazoo

DONNA SOCHA NOTARY PUBLIC STATE OF MICHIGAN County of Kalamazoo MY COMMISSION EXPIRES MAR 17, 2029

Employee Contingent List at 6300

Workday ID	First Name	Last Name	Worker Type	Location
1465429	Robert	Haan	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1465011	Brenda	Trinh	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1465314	Travis	Young	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1465171	Kenneth	Dean	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1465162	Jeffrey	Wesaw	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1463840	Nathan	Mann	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1465147	Jerry	Garrett	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1465639	Jamie	Saddler	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1464082	David	Beilby	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1463900	Laura	Norman	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1458529	Kenneth	Rule	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1465637	Benjamin	Carroll	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1501535	Richard	Bassett	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
3298550	Nelysha	Torres	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
6067786	Robert	Strong	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
6958967	Daniel	Sager	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
6799811	Jacob	Mikel	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
6970034	Neil	Stuut	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
7139217	Matthew	Williams	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
7027045	Daniel	Lasecki	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
7192829	Kyle	Lynes	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
7193775	Brandy	Hernandez	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
7198237	Cailey	Welch-Wilder	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
7218311	Eric	Korsedal	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1003138	Stew	Miller	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
7195053	Chelsea	Uildriks	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1006787	Alex	Bobon	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
7188843	Nathan	Carango	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1010942	Kimberly	Crane	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1005356	Evan	Charron	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1004349	Sarah	Lancaster	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1013211	Nicholas	Hurst	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1008098	Daniel	Switalski	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1023201	Justin	Lewis	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1016637	Justin	Dumois	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1013977	Tyler	Rawlinson	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1026395	Douglas	Waltz	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1026851	Maksymilian	Paprocki	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1015626	Joshua	Fleisher	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1029441	Zane	Buys	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1033577	Mark	Curtis	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1024254	Dominick	Goetting	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1029325	Megan	Hackenberg	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1034186	Juan	Martinez	Contingent Worker	Michigan, Kalamazoo 6300 South Sprinkle Rd
1034611	Francisco	Vega	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1034791	Tanner	Brauer	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1035364	Brittany	Shaw	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1035181	Walter	Allen	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1027351	Michael	Wilson	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1036039	Linda	Hoppenrath	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1037579	Austin	Paterson	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1042135	Jacqueline	Laude	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1043377	Rachel	Richman	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1043612	Duncan	McNabb	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1044466	Jacob	Syers	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd

Employee Contingent List at 6300

Workday ID	First Name	Last Name	Worker Type	Location
1046217	Devin	Kopec	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
7152374	Hannah	Rohn	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1049485	Dayon	Neals	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1022422	Hailie	Launius	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1050495	Fred	Page Jr	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1051662	Felicity	Palmer	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1051989	Cameron	Kosmerick	Employee	Michigan, Kalamazoo 6300 South Sprinkle Rd
1051784	Kevin	Frey	Contingent Worker	Michigan, Kalamazoo 6300 South Sprinkle Rd

Nevada Section 2: History of Company

Qualifiers:

3: Applicant does not manufacture/distribute pharmaceuticals.

4: Applicant does not manufacture/distribute controlled substances.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

OR

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

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

- **Integrity** — We do what's right
- **Accountability** — We do what we say
- **People** — We grow talent
- **Performance** — We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,589	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,848	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,189	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,108	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	$ 3,888	$ 2,841	$ 2,584	$ 2,223	$ 2,713
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	$ 3,673	$ 2,683	$ 2,281	$ 1,954	$ 2,562
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

	2023	2022	2021	Percent Net Sales 2023	Percent Net Sales 2022	Percent Net Sales 2021	Percentage Change 2023 vs. 2022	Percentage Change 2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

Dollar amounts in millions except per share amounts or as otherwise specified.

4J

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: Stryker Corporation

Physical Address: 3800 E. Centre Ave

City: Portage State: MI Zip: 49002

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 269-838-5962 Website: www.stryker.com

Name of Designated Representative (DR): James Tuohy

Licensing Company Email: statelicensing1@stryker.com DR Email: james.tuohy@gmail.com

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

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

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/3/24.
Date

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

Name: Not Applicable-no pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: MI

Parent Company (if any): N/A

Corporation Name: Stryker Corporation

Mailing Address: 1941 Stryker Way

City: Portage State: MI Zip: 49002

Telephone: 269-838-5962 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979	SEC Registration Number: 001-13149	Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

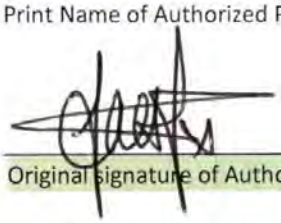
I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application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

Stryker Corporation

Facility Name

James Tuohy

Print Name of Authorized Person Submitting Application



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

6/3/24.

Date

Board Use Only	Date Received: 6/24/24	Amount: $1000-CH17757

Nevada Section 2: History of Company

Qualifiers:

3: Applicant does not manufacture/distribute pharmaceuticals.

4: Applicant does not manufacture/distribute controlled substances.

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
STRYKER MEDICAL
3800 E. CENTRE AVE.
Portage, MI 49002
Registration Number: 1831750
FEI Number*: 1831750
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Divya Murali
Stryker
3800 E. Centre Ave
Portage, MI 49002
Phone: 1-269-5678254

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

Verified M.H 6/18/24

Links on this page:
1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

Page Last Updated: 05/13/2024

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Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph, 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance
State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

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4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

Stryker Corp.	
Name	**Role**
Fletcher, Robert S.	Officer
Lobo, Kevin A.	Officer & Director
Menon, Viju S.	Officer
Pierce, J. Andrew	Officer
Stiles, Spencer S.	Officer
Name	**Board of Directors**
McCoy, Sherilyn	Director
Brainerd, Mary	Director
Caforio MD, Giovanni	Director
Datar PhD., Srikant	Director
Golston, Allan	Director
Silvernail, Andrew	Director
Skeete Tatum, Lisa	Director
Styker, Ronda	Director
Suri, Rajeec	Director
Name	**List of Top 4 Shareholders & Percentages**
The Vanguard	8.2%
Group BlackRock Inc	6.6%
John W. Brown	5.3%

Incorp State Good Standing

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

STRYKER CORPORATION

was validly incorporated on February 20 , 1946 as a Michigan DOMESTIC PROFIT CORPORATION, and said corporation is validly in existence under the laws of this state.

This certificate is issued pursuant to the provisions of 1972 PA 284 to attest to the fact that the corporation is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS ★ Corporations, Securities & Commercial Licensing Bureau ★

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 1st day of May , 2024.

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24050010410

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

Home State License

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

5306007311APP22

STRYKER CORPORATION
3800 E CENTRE AVE
PORTAGE, MI 49002

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

STRYKER CORPORATION
3800 E CENTRE AVE
PORTAGE, MI 49002

LICENSE NO.
5306007311

EXPIRATION DATE
03/08/2025

23067140356

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Stryker Corporation & Subsidiaries 1941 Stryker Way Portage MI 49002 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	Y/N			AOS				
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A		MWXS31274524	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
	(Mandatory in NH)			Excess WC - MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

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

FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570103677315

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Stryker Corporation — MDEG License # (if applicable): Not applicable

Physical Address: 3800 E. Centre Ave

City: Portage — State: MI — Zip: 49002

Mailing Address (if different from physical address): Same as physical address

City: — State: — Zip:

Telephone: 269-838-5962 — Website: https://stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: James — Middle: Paul — Last: Tuohy

Alias(es, nicknames, name changes, etc.): Not applicable

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

Mailing Address: [redacted] Kellison Drive

City: Kalamazoo — State: MI — Zip: 49009

Telephone: 269-838-5962 — Email: james.tuohy@stryker.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Western Michigan University		2007-2008	
Address	**City**	**State**	**Zip**
1903 W Michigan Ave	Kalamazoo	MI	49008
Diploma/Degree obtained, if any			
M.S. Manufacturing Engineering			

School Name		From - To (MM/YY – MM/YY)	
National University of Ireland, Galway		1997-2002	
Address	**City**	**State**	**Zip**
University Road	Galway, Ireland		H91 TK33
Diploma/Degree obtained, if any			
B.E. Mechanical Engineering			

School Name		From - To (MM/YY – MM/YY)	
St. Caimins Community School		Sep 02 - Jun 97	
Address	**City**	**State**	**Zip**
Tullyvarraga, Shannon	Clare, Ireland		V14XY54
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/2016 - present	[redacted] Kellison Drive	Kalamazoo	MI	49009
5/2013 - 4/2016	[redacted] Grand Pre Ave	Kalamazoo	MI	49006

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

Business Name: Stryker Corporation				From - To (MM/YY – MM/YY): 08/17-Present
Business Address: 3800 E. Centre Ave		City: Portage	State: MI	Zip: 49002
Phone: 269-838-5962	Title: Director, Divisional Quality Assurance			Number of Employed Hours: 12,000+
Description of Duties: See attached resume				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

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

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/3/24
Date

I, James Tuohy, certify that as the MDEG Administrator for

Stryker Corporation,

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

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

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Tuohy
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/3/24
Date

Board Use Only	Date Received: 6/24/24

JAMES PAUL TUOHY

Address: [redacted] Kellison Drive, Kalamazoo, MI 49009 [redacted]

Aug 2017 – Present, Stryker Medical, 3800 East Centre Ave, Portage, Michigan
Title: Director, Divisional Quality Assurance

May 2014 – Aug 2017, Ranir LLC, Grand Rapids, Michigan
Title: Quality Manager, North America (May 2014 – Oct 2016)
Title: Sr. Quality Assurance & Post Market Surveillance Manager (Oct 2016 – Aug 2017)
Duties: Responsible for entire QA / QC functions at the Grand Rapids facility. Active and engaged leader of all QC Lab, Quality Tech and Quality Engineering team members (Total of seventeen employees). Development of strategies for more proactive QA engineering approach including improvements to Internal Audit, CAPA, Complaint Handling and NCR processes. Greater visibility and exposure to all elements of the quality system as a result of a smaller, growing company. Day to day risk-based decision maker as it relates to compliance for a complex portfolio of products ranging from Class I & II devices, OTC, cosmetics and consumer goods. Site lead for ISO 13485, 9001 and BRC certification in addition to multiple and frequent large US retailer visits and audits. Designate management representative for the Grand Rapids facility.

Aug 2012 – May 2014, Zimmer Orthopaedics Inc., Warsaw, Indiana
Title: Associate Director Quality Assurance, Zimmer Orthopaedic Implant Manufacturing
Duties: Responsible for Quality Assurance function for all Warsaw manufacturing facilities. Active and engaged leader of more than twenty-five talented Quality staff, ranging from technician to principal and manager level positions. Development of strategies for more proactive QA engineering approach and of leading KPI metrics developed and aligned with operations and other cross functional groups. CAPA committee associate site lead, driving effectiveness of investigation, consistency of escalation and timeliness. Owner of Warsaw site tracker driving timely communication of all emerging production issues to executive management, detailing immediate containment required, concise investigation plan and path to resolution.

Jan 2011 – Aug 2012, Zimmer Orthopaedics Inc., Warsaw, Indiana
Title: Quality Engineering Manager, Zimmer Reconstructive Manufacturing, Warsaw
Duties: Responsible for all Reconstructive Manufacturing and Validation Quality support at Warsaw facility. Manage a team of twenty Engineers responsible for Hip, Knee, Extremity and Instrument value stream Quality support. Given the opportunity to level load manufacturing resources and to restructure and develop new Quality Engineering role and implement more powerful training assignments post company re-org. Drive more consistent leading metrics and champion Six Sigma initiative for continual improvement. High level decision maker regarding process deviations, accept as is dispositions and high risk failures

Jan 2008 – Jan 2011, Zimmer Orthopaedics Inc., Warsaw, Indiana
Title: Senior Quality Engineer II, Global Network Optimization / Transfer Team
Duties: Quality Assurance leader for Global Manufacturing Transfer Team. Responsible for the implementation of Quality System at new plant location / start up and Transfer (Ireland and Puerto Rico). Validation cycle implementation and execution at the new manufacturing location. Extensive Cross functional participation as required for a new large scale start up. Worked with local management team on initial plant certification and registration (BSI, Certificate of Free sale and PMA submission).

JAMES PAUL TUOHY

Address: [redacted] Kellison Drive, Kalamazoo, MI 49009 [redacted]

Summer 2007 (During Masters Study): DePuy, A Johnson & Johnson Company, Indiana
Title: Manufacturing Engineer (Orthopaedic Class III Medical Device Manufacture)

Duties: Process development and implementation of proven technologies at US site.

Jan 2004 – Jan 2007: DePuy, A Johnson & Johnson Company, Cork, Ireland
Title: Process Engineer (Orthopaedic Class III Medical Device Manufacture)
Duties: Consistently delivered on process improvement projects across the business unit resulting in significant scrap / reprocessing reduction, consumable savings, ergonomic improvements and increased capacity. Introduction and validation of a new automated, high volume lapping process replacing manual grind / prep and polishing steps. Completion, review and submission of several PMA supplements required by FDA guidelines for manufacturing changes and process automation.

June 2003 – Jan 2004 (6 month contract): Quality Engineer, Molex Ireland, Shannon, County Clare.
Duties: Supporting role for Quality department, hold disposition, complaint handling, FMEA creation.

April - Sep 2001: Co-Op Engineer, De Beers Industrial Diamond Division, Shannon, County Clare.
Duties: CNC programming. Fixture design and process development of new lapping process.

Projects and Leadership:

- *FDA Inspection Lead:* Front and backroom lead for several BSI, Korea FDA and multiple US FDA Level II and follow up inspections. Familiar with best practice for request preparation, review and submission to inspector and 483 response. Familiar with best practice for backroom communication and preparation.

- *Comprehensive Site Validation Assessment and Restructure:* As part of remediation activity across Warsaw facility, a comprehensive risk based review of all process validation projects onsite took place via interim control. This assessment was designed to identify those projects that were deficient in relation to safety and efficacy and required immediate containment and revalidation.

- *Supplier Engagement Initiative:* Participated and led Quality portion of an Asian Supplier summit in Shanghai as Ranir LLC Quality Manager. The purpose of the summit was to develop supplier relationships and heavily engage suppliers. During the summit expectations regarding service, quality and delivery were highlighted including new expectations for effective Corrective Action, Root Cause Investigation & Change Management.

- *Risk Management:* Dual site manufacturing posed a challenge to the Zimmer Risk Management system where mirror processes in different locations were not analysed together, leaving discrepancies between the two sites scoring of risk. I proposed and implemented a new method of analysing risk at new locations while still accounting for the same process at other sites.

Further Skills and Training:

- Proficient in GMP, SPC, CAPA, GD&T, FMEA and Six Sigma / DMAIC methodology
- AAMI QSR, Process Validation, CAPA and Design Control training complete

Education:

2007 - 2008: ***M.S Manufacturing Engineering (GPA 3.65),*** Western Michigan University, MI
1997 - 2002: ***B.E Mechanical Engineering (2nd Hons),*** National University of Ireland, Galway
2006: ***Certified Six Sigma Black Belt,*** Johnson & Johnson Process Excellence Program, UK
2018: ***Certified ISO 13485 lead auditor*** – Oriel STAT A MATRIX

3800 Centre
Tuohy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Stryker Corporation

Pharmacy/Wholesaler License # (if applicable): Not applicable

Physical Address: 3800 E. Centre Ave

City: Portage State: MI Zip: 49002

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 269-838-5962 Website: https://stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: James Middle: Paul Last: Tuohy

Alias(es, nicknames, name changes, etc.): Not applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Kellison Drive

City: Kalamazoo State: MI Zip: 49009

Telephone: 269-838-5962 Email: james.tuohy@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Western Michigan University			2007-2008	
Address		City	State	Zip
1903 W Michigan Ave		Kalamazoo	MI	49008
Diploma/Degree obtained, if any				
M.S. Manufacturing Engineering				
School Name			From - To (MM/YY – MM/YY)	
National University of Ireland, Galway			1997-2002	
Address		City	State	Zip
University Road		Galway, Ireland		H91 TK33
Diploma/Degree obtained, if any				
B.E. Mechanical Engineering				
School Name			From - To (MM/YY – MM/YY)	
St. Caimins Community School			1992 - 1997	
Address		City	State	Zip
Tullyvarraga, Shannon		Clare, Ireland		V14XY54
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/2016 - present	4/2016 - present	Kalamazoo	MI	49009
5/2013 - 4/2016	532 Grand Pre Ave	Kalamazoo	MI	49006

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Stryker Corporation				From - To (MM/YY – MM/YY): 08/17-Present
Business Address: 3800 E. Centre Ave		City: Portage	State: MI	Zip: 49002
Phone: 269-838-5962	Title: Director, Divisional Quality Assurance			Number of Employed Hours: 12,000+
Description of Duties: See attached resume				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? Not applicable		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

06/13/24
Date

I, James Tuohy, **certify that as the designated representative for**

Stryker Corporation,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. FT I am at least 21 years of age;
3. FT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. FT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. FT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. FT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. FT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

James Tuohy
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/13/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Tuohy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/13/24

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Kalamazoo

I, James Tuohy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature James Tuohy

06/13/24

Date

Subscribed and Sworn to before me this 13th day of June.

Nitasha Dominowski

Notary Public Signature

Nitasha Dominowski
NOTARY PUBLIC
COUNTY OF KALAMAZOO
My Commission Expires
14-December-2029
Acting in the County of
Kalamazoo
STATE OF MICHIGAN
(Seal)

Worker Roster General

Organizations Michigan
Include Subordin Yes
Effective as of Date

3800 E. Centre Ave, Portage, MI

List of employees and contractors

Workday ID	First Name	Last Name	Email - Work	Preferred Name
1463986	Terry	Vandiver	terry.vandiver@stryker.com	Terry Vandiver
1463623	Cheryl	Cook	cheryl.cook@stryker.com	Cheryl Cook
1463756	Thomas	Herder	thomas.herder@stryker.com	Tom Herder
1463745	Mary	Bagi	mary.bagi@stryker.com	Mary Bagi
1464019	Bonnie	Robinson	bonnie.robinson@stryker.com	Bonnie Robinson
1462910	Robert	McBarnes	bob.mcbarnes@stryker.com	Bob McBarnes
1463784	Louis	Garza	lou.garza@stryker.com	Louis Garza
2300525	Brian	Orwat	brian.orwat@stryker.com	Brian Orwat
1463722	Mark	McCrorey	mark.mccrorey@stryker.com	Mark McCrorey
1461309	Krista	Antonowitsch	kris.antonowitsch@stryker.com	Krista Antonowitsch
1464670	Kenneth	Tompkins	ken.tompkins@stryker.com	Kenneth Tompkins
1462919	William	Kleczynski	bill.kleczynski@stryker.com	Bill Kleczynski
1464029	Tommy	Roberson	tommy.roberson@stryker.com	Tom Roberson
1462928	Christopher	Hopper	chris.hopper@stryker.com	Chris Hopper
1463747	Dennis	Ingold	dennis.ingold@stryker.com	Dennis Ingold
1462933	Michael	Hayes	mike.hayes@stryker.com	Mike Hayes
1464033	Nickolas	Finch	nick.finch@stryker.com	Nick Finch
1463764	Edward	Hamilton	edward.hamilton@stryker.com	Ed Hamilton
1463782	Rodney	Francisco	rod.francisco@stryker.com	Rod Francisco
1464016	David	Seelbinder	david.seelbinder@stryker.com	David Seelbinder
1463762	Todd	Hartman	todd.hartman@stryker.com	Todd Hartman
1463972	John	Zerbel	john.zerbel@stryker.com	John Zerbel
1463625	Timothy	Clements	timothy.clements@stryker.com	Tim Clements
1462942	Aaron	Gamache	aaron.gamache@stryker.com	Aaron Gamache
1463606	Dickson	Brubaker	dickson.brubaker@stryker.com	Dickson Brubaker

3800 E. Centre Ave, Portage, MI

List of employees and contractors

Workday ID	First Name	Last Name	Email - Work	Preferred Name
1463611	Steven	Birman	steve.birman@stryker.com	Steve Birman
1463969	James	Zerbel	jim.zerbel@stryker.com	Jim Zerbel
1462903	Bradford	Saar	brad.saar@stryker.com	Brad Saar
1463772	Kenneth	Griffin	kenneth.griffin@stryker.com	Ken Griffin
1463737	David	Kirby	david.kirby@stryker.com	David Kirby
1462941	Marc	Goodwin	marc.goodwin@stryker.com	Marc Goodwin
1463982	Kelli	Craddock	kelli.craddock@stryker.com	Kelli Craddock
1463740	Thomas	Kinnison	tom.kinnison@stryker.com	Thomas Kinnison
1463726	Todd	McCurdie	Todd.McCurdie@stryker.com	Todd McCurdie
1464008	Kenneth	Smith	kenneth.smith@stryker.com	Kenny Smith
1464013	Nathan	Steele	nathan.steele@stryker.com	Nathan Steele
1465052	Demetrius	Givhan	demetrius.givhan@stryker.com	Demetrius Givhan
1462887	Thomas	Tackabury	tom.tackabury@stryker.com	Tom Tackabury
1464114	Timothy	Campbell	tim.campbell@stryker.com	Tim Campbell
1463987	Hans	Vander Gronden	hans.vandergronden@stryker.com	Hans Vander Gronden
1463610	Terry	Bontrager	terry.bontrager@stryker.com	Terry Bontrager
1463734	Leslie	Malone	leslie.malone@stryker.com	Les Malone
1463714	Gloria	Perry	gloria.perry@stryker.com	Gloria Perry
1464107	Brian	Davis	brianc.davis@stryker.com	Brian Davis
1459289	Brian	Uline	Brian.Uline@stryker.com	Brian Uline
1462932	Michael	Hernandez	mike.hernandez@stryker.com	Mike Hernandez
1463057	Xianyu	Shea	Xianyu.Shea@stryker.com	Xianyu Shea
1463600	Todd	Alberda	todd.alberda@stryker.com	Todd Alberda
1463738	Carl	Krohn	carl.krohn@stryker.com	Carl Krohn
1464027	Thomas	Reynolds	tom.reynolds@stryker.com	Tom Reynolds
1464014	Sandra	Smith	sandy.smith@stryker.com	Sandy Smith
1462943	Jamie	Flickinger	Jamie.Flickinger@stryker.com	Jamie Flickinger
1463980	Matthew	Wall	matt.wall@stryker.com	Matthew Wall
1464119	Larry	Burchard	larry.burchard@stryker.com	Doug Burchard Jr
1464124	Shaun	Berkheiser	shaun.berkheiser@stryker.com	Shaun Berkheiser

3800 E. Centre Ave, Portage, MI

List of employees and contractors

Workday ID	First Name	Last Name	Email - Work	Preferred Name
1462871	Kerri	Carpenter	kerri.carpenter@stryker.com	Kerri Carpenter
1462907	Kevin	Patmore	kevin.patmore@stryker.com	Kevin Patmore
1464438	Scott	Zufall	scott.zufall@stryker.com	Scott Zufall
1463767	Michael	Hamelink	michael.hamelink@stryker.com	Michael Hamelink
1463978	Eugene	Weeks	chip.weeks@stryker.com	Chip Weeks
1463050	William	Childs	will.childs@stryker.com	Will Childs III
1463742	Luis	Juarez	luis.juarez@stryker.com	Luis Juarez
1465614	Timothy	Ohmer	tim.ohmer@stryker.com	Timothy Ohmer
1464924	Daniel	DesRosiers	dan.desrosiers@stryker.com	Daniel DesRosiers
1463787	Roger	Francisco	roger.francisco@stryker.com	Roger Francisco
1464121	Trent	Beall	trent.beall@stryker.com	Trent Beall
1463997	Tom	Szymanski	tom.szymanski@stryker.com	Tom Szymanski
1463995	Marcie	Tiller	marcie.tiller@stryker.com	Marcie Tiller
1463853	John	Metheny	john.metheny@stryker.com	John Metheny
1463850	Jessica	Terpstra	jessica.terpstra@stryker.com	Jessica Terpstra
1463851	Sara	Kline	sara.kline@stryker.com	Sara Kline
1463636	Shawn	Howard	shawn.howard@stryker.com	shawn Howard
1462856	Richard	Derenne	richard.derenne@stryker.com	Richard Derenne
1462857	Melissa	Centofanti	melissa.centofanti@stryker.com	Melissa Centofanti
1462854	Kimber	Atteberry	kimber.atteberry@stryker.com	Kimber Atteberry
1461292	Mary	Klaver	mary.klaver@stryker.com	Mary Klaver
1463845	Jeffrey	Granado	jeff.granado@stryker.com	Jeff Granado
1462851	Brett	Simmering	brett.simmering@stryker.com	Brett Simmering
1463833	Chad	Mott	chad.mott@stryker.com	Chad Mott
1463838	Paul	Martin	paul.martin2@stryker.com	Paul Martin
1463831	Cynthia	Osborn	cindi.osborn@stryker.com	Cindi Osborn
1463828	Michael	Mosquera	michael.mosquera@stryker.com	Mike Mosquera
1463825	Peter	Tonthola	peter.tonthola@stryker.com	Pete Tonthola
1463827	Jack	Lard	jack.lard@stryker.com	Jack Lard
1463820	Emmy	Waldo	emmy.waldo@stryker.com	Emmy Waldo
1463812	Jeremiah	Johnson	jeremiahl.johnson@stryker.com	Jeremiah Johnson
1463810	Beth	Watson	beth.watson@stryker.com	Beth Watson

3800 E. Centre Ave, Portage, MI

List of employees and contractors

Workday ID	First Name	Last Name	Email - Work	Preferred Name
1372898	Eamonn	Nestor	Eamonn.Nestor@stryker.com	Eamonn Nestor
1464323	Anthony	Dowson	tony.dowson@stryker.com	Anthony Dowson
1463805	Brian	Tessmer	brian.tessmer@stryker.com	Brian Tessmer
1463802	Edith	Blaksley	edith.clark@stryker.com	Char Clark
1462832	Vasanthkumar	Subramanian	vas.subramanian@stryker.com	Vas Subramanian
1465222	Tina	Wentzel	tina.wentzel@stryker.com	Tina Wentzel
1465220	Meoshi	Atkinson	meoshi.atkinson@stryker.com	Meoshi Atkinson
1462798	Brandon	Naber	brandon.naber@stryker.com	Brandon Naber
1462791	Paul	Radgens	paul.radgens@stryker.com	Paul Radgens
1462794	James	Dorff	jim.dorff@stryker.com	Jim Dorff
1463786	Troy	Cosgrove	troy.cosgrove@stryker.com	Troy Cosgrove
1462793	Kurosh	Nahavandi	kurosh.nahavandi@stryker.com	Kurosh Nahavandi
1462790	Anish	Paul	anish.paul@stryker.com	Anish Paul
1463783	Katherine	Webb	kathy.webb@stryker.com	Kathy Webb
1463967	Brian	Thompson	brianw.thompson@stryker.com	Brian Thompson
1463966	Phillip	Ortiz	phillip.ortiz@stryker.com	Phil Ortiz
1463963	Gwendolyn	Monroe	gwen.monroe@stryker.com	Gwen Monroe
1463964	Bilal	Farran	bill.farran@stryker.com	Bill Farran
1463959	Kelly	LaFave	Kelly.LaFave@stryker.com	Kelly LaFave
1463952	Steven	Finn	steven.finn@stryker.com	Steven Finn
1463956	Alexander	Slawinski	alexander.slawinski@stryker.com	Alex Slawinski
1463957	Jean	Dodes	jean.dodes@stryker.com	Jean Dodes
1465189	Andrea	Martin	andrea.martin@stryker.com	Andrea Martin
1462769	Dominic	Centofanti	ron.centofanti@stryker.com	Ron Centofanti
1463949	Christopher	Kuras	christopher.kuras@stryker.com	Chris Kuras
1463951	Christopher	Quayle	christopher.quayle@stryker.com	Chris Quayle
1462768	Joshua	Mix	josh.mix@stryker.com	Joshua Mix
1463946	Sharon	Hendershot	sharon.hendershot@stryker.com	Sharon Hendershot
1463947	Ryan	Needham	ryan.needham@stryker.com	Ryan Needham

3800 E. Centre Ave, Portage, MI

List of employees and contractors

Workday ID	First Name	Last Name	Email - Work	Preferred Name
1462757	Stephanie	Trevino	stephanie.trevino@stryker.com	Stephanie Trevino
1463941	Michael	Symko	mike.symko@stryker.com	Michael Symko
1463945	Harold	Schiedel	harold.schiedel@stryker.com	Harold Schiedel
1464219	Kapil	Mehra	Kapil.Mehra@stryker.com	Kapil Mehra
1463937	Carrie	Howard	carrie.howard@stryker.com	Carrie Howard
1464210	Scott	Sagehorn	scott.sagehorn@stryker.com	Scott Sagehorn
1462746	Cory	Herbst	cory.herbst@stryker.com	Cory Herbst
1463932	Kenneth	Lemmer	kenneth.lemmer@stryker.com	Ken Lemmer
1463629	Ted	Hilliard	ted.hilliard@stryker.com	Ted Hilliard
1463633	Eulian	Osborne	randy.osborne@stryker.com	Randy Osborne
1463624	Chad	Mellis	chad.mellis@stryker.com	Chad Mellis
1464180	Michael	Peterson	Michael.Peterson@stryker.com	Michael Peterson
1464096	Joseph	Gearhart	joe.gearhart@stryker.com	Joe Gearhart
1462577	Jeffrey	SaintJohn	jeff.stjohn@stryker.com	Jeff SaintJohn
1463709	Christine	Bickel	chrissy.bickel@stryker.com	Chrissy Bickel
1463702	Travis	Lantis	travis.lantis@stryker.com	Travis Lantis
1463706	William	Teunissen	william.teunissen@stryker.com	William Teunissen
1463711	Stacy	Stimac	stacy.stimac@stryker.com	Stacy Stimac
1463022	Tara	Lawson	tara.lawson@stryker.com	Tara Lawson
1463700	Laura	Hawthorne	laura.hawthorne@stryker.com	Laura Hawthorne
1464996	Jonathan	Bailey	jon.bailey@stryker.com	Jon Bailey
1462581	Gina	Schiming	gina.schiming@stryker.com	Gina Schiming
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1463698	Harrison	McCullough	harrison.mccullough@stryker.com	Harrison McCullough
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1463688	Claylee	Rhoades	clay.rhoades@stryker.com	Clay Rhoades
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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1463687	Karen	Fall	karen.fall@stryker.com	Karen Fall
1462583	Aaron	Furman	aaron.furman@stryker.com	Aaron Furman
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3295422	Annette	Hillman	Annette.Hillman@stryker.com	Annette Hillman
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5047787	Melvin	Gottschalk	melvin.gottschalk@stryker.com	JR Gottschalk Jr
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

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1023377	Trent	Schultz	trent.schultz@stryker.com	Trent Schultz
1023379	Courtney	McCauley	courtney.mccauley@stryker.com	Courtney McCauley
1023610	Jamie	Leiterman	jamie.leiterman@stryker.com	Jamie Leiterman
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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7159192	Jacob	Pickern	JACOB.PICKERN@stryker.com	Jacob Pickern
1023460	Morgan	Miller	morgan.miller@stryker.com	Morgan Miller
1024086	Sarah	Jozwiak	sarah.jozwiak@stryker.com	Sarah Jozwiak
1024088	Ashley	Conklin	ashley.conklin@stryker.com	Ashley Conklin
1024388	Matt	Saucedo	matt.saucedo@stryker.com	Matt Saucedo
1024444	Brian	Ignacek	brian.ignacek@stryker.com	Brian Ignacek
1024073	Michele	Koopman	michele.koopman@stryker.com	Michele Koopman
1024145	Paul	Koopman	paul.koopman@stryker.com	Paul Koopman
1024171	Deepika	Ekurthi	deepika.ekurthi@stryker.com	Deepika Ekurthi
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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7149209	Rachel	Stockwell	rachel.stockwell@stryker.com	Rachel Stockwell
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1026132	Ashley	Streeter	ashley.streeter@stryker.com	Ashley Streeter
1026324	Charles	Wilson	charles.wilson3@stryker.com	Chuck Wilson
1026350	Sherry	Chapel	sherry.chapel@stryker.com	Sherry Chapel
1026461	Nolan	Holland	nolan.holland@stryker.com	Nolan Holland
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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1051228	Matthew	Stuckey	matthew.stuckey@stryker.com	Matthew Stuckey
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1051244	Kenneth	Smith	kenneth.smith1@stryker.com	Kenneth Smith
1051245	Melissa	Palumbo	melissa.palumbo@stryker.com	Melissa Palumbo
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1051239	Evelyn	Hinkley	evelyn.hinkley@stryker.com	Evelyn Hinkley
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1051375	Anjel	Johnson	anjel.johnson@stryker.com	Anjel Johnson
1051388	Ashli	Knight	ashli.knight@stryker.com	Ashli Knight
1051404	Treyvian	Lewis	treyvian.lewis@stryker.com	Treyvian Lewis
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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1051490	Desiree	Felton	desiree.felton@stryker.com	Desiree Felton
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

Workday ID	First Name	Last Name	Email - Work	Preferred Name
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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1047381	Cortland	Hasenburg	cortland.hasenburg@stryker.com	Cortland Hasenburg
1052841	Ricardo	Alcaraz-zarco	ricardo.alcaraz-zarco@stryker.com	Ricardo Alcaraz-zarco
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3800 E. Centre Ave, Portage, MI

List of employees and contractors

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1052671	Tyrice	Trigg	tyrice.trigg@stryker.com	Tyrice Trigg
1052669	Vholeerie	Petrova	vholeerie.petrova@stryker.com	Vholeerie Petrova
1052670	Jabir	Hardie	jabir.hardie@stryker.com	Jabir Hardie
1052743	Ronald	Allen	ronald.allen1@stryker.com	Ronald Allen
1052825	Davontae	Jackson	davontae.jackson@stryker.com	Davontae Jackson
1052763	Chianne	Dentler	chianne.dentler@stryker.com	Chianne Dentler
1048645	Sara	Patton	sara.patton@stryker.com	Sara Patton
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1039856	Christopher	Jones	chris.jones4@stryker.com	Chris Jones
1052045	Trinity	Purdiman	trinity.purdiman@stryker.com	Trinity Purdiman
1052604	Teresa	Ruiz	teresa.ruiz@stryker.com	Teresa Ruiz
1052826	Kamarey	Williams	kamarey.williams@stryker.com	Kamarey Williams
1052904	Derek	Tison	derek.tison@stryker.com	Derek Tison
1052972	Denise	Peterson	denise.peterson@stryker.com	Denise Peterson
1053010	Diamond	Sawyer	diamond.sawyer@stryker.com	Diamond Sawyer
1053070	Eric	Carriger	eric.carriger@stryker.com	Eric Carriger
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

- **Integrity** – We do what's right
- **Accountability** – We do what we say
- **People** – We grow talent
- **Performance** – We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,589	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,846	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,189	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

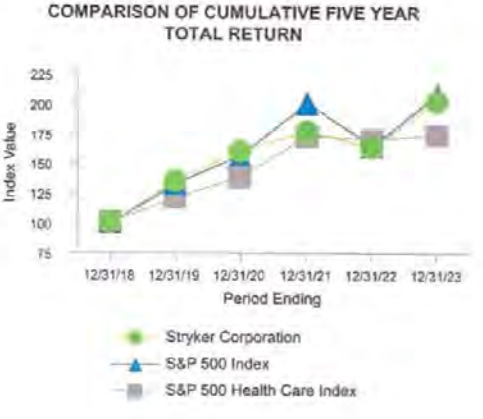
Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,108	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	$ 3,888	$ 2,841	$ 2,584	$ 2,223	$ 2,713
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	$ 3,673	$ 2,683	$ 2,281	$ 1,954	$ 2,562
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	**$ 20,498**	**$ 18,449**	**$ 17,108**	**100.0 %**	**100.0 %**	**100.0 %**	**11.1 %**	**7.8 %**
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	16	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	**$ 3,165**	**$ 2,358**	**$ 1,994**	**15.4 %**	**12.8 %**	**11.7 %**	**34.2 %**	**18.3 %**
Net earnings per diluted share	**$ 8.25**	**$ 6.17**	**$ 5.21**				**33.7 %**	**18.4 %**
Adjusted net earnings per diluted share[1]	**$ 10.60**	**$ 9.34**	**$ 9.09**				**13.5 %**	**2.8 %**

nm - not meaningful

Dollar amounts in millions except per share amounts or as otherwise specified.

4K

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Stryker Corporation

Physical Address: 47900 Bayside Parkway

City: Fremont State: CA Zip: 94536

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 408-821-1370 Website: www.stryker.com

Name of Designated Representative (DR): Carol Jane Romero

Licensing Company Email: statelicensing1@stryker.com DR Email: carol.romero@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Not Applicable-no pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: MI

Parent Company (if any): N/A

Corporation Name: Styker Corporation

Mailing Address: 47900 Bayside Pkwy

City: Fremont State: CA Zip: 94536

Telephone: 214-287-4694 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Stryker Corporation

Facility Name

Carol Jane Romero

Print Name of Authorized Person Submitting Application

Carol Romero

Original signature of Authorized Person (copies or stamps not accepted)

11 Apr 2024

Date

Board Use Only	Date Received: 6/24/24	Amount: $1000 ck 12757

Nevada Section 2: History of Company

Qualifiers:

3: Applicant does not manufacture/distribute pharmaceuticals.

4: Applicant does not manufacture/distribute controlled substances.

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538
Registration Number: 3008853977
FEI Number*: 3008853977
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Jennifer Mateus
Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538
Phone: 510-4132752

Verified 6/26/24 M.H

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 05/20/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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Stryker Corp.

Name	Role
Fletcher, Robert S.	Officer
Lobo, Kevin A.	Officer & Director
Menon, Viju S.	Officer
Pierce, J. Andrew	Officer
Stiles, Spencer S.	Officer

Name	Board of Directors
McCoy, Sherilyn	Director
Brainerd, Mary	Director
Caforio MD, Giovanni	Director
Datar PhD., Srikant	Director
Golston, Allan	Director
Silvernail, Andrew	Director
Skeete Tatum, Lisa	Director
Styker, Ronda	Director
Suri, Rajeec	Director

Name	List of Top 4 Shareholders & Percentages
The Vanguard	8.2%
Group BlackRock Inc	6.6%
John W. Brown	5.3%

Incorp State Good Standing

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

STRYKER CORPORATION

was validly incorporated on February 20 , 1946 as a Michigan DOMESTIC PROFIT CORPORATION, and said corporation is validly in existence under the laws of this state.

This certificate is issued pursuant to the provisions of 1972 PA 284 to attest to the fact that the corporation is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 1st day of May , 2024.

Linda Clegg

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24050010410

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Stryker Corporation
47900 Bayside Pkwy
Fremont, CA 94538

LICENSE NUMBER: 55190
EXPIRATION DATE: 5/5/2026

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 4/25/2024

0565

Home State License

Home State License
Official Verification

State of California—Health and Human Services Agency
California Department of Public Health

Food and Drug Branch
P.O. Box 997435, MS 7602
Sacramento, CA 95899-7435
1-800 495-3232 Toll Free

LICENSE / REGISTRATION VERIFICATION REQUEST

Requestor: Complete Items 1-6 only, then forward to California Department of Public Health, Food and Drug Branch at the address above.

1. Name of Firm or Exemptee / DBA Stryker Corporation			
2. Facility Address (number, street) 47900 Bayside Parkway			
3. City Fremont	State CA		Zip Code 94538
4. Type of Firm ☐ Retailer ☐ Warehouse ☑ Manufacturer			
5. Requestor's Name Wendie Nonclerc			
6. Requestor's Address			
City	State	ZIP Code	Email statelicensing1@stryker.com
Requestor's Mailing Address (if different or P.O. Box number) 705 Montgomery Ave #200			
City Penn Valley	State PA	ZIP Code 19072	

DO NOT WRITE BELOW THIS LINE – TO BE COMPLETED BY STATE AGENCY

License Type	License Number	Date Issued	Expiration Date
Medical Device	55190	5/5/2011	5/5/2026

License / Registration Status:

☒ **Valid** ☐ **Suspended/Revoked** ☐ **Surrendered** ☐ **Expired**

☐ **No record of firm / individual** ☐ **Application received / license pending**

Official Signature/Title: Drug and Medical Device Safety Analyst Date: 5/20/2024

Emily Chu

CDPH 8707 (02/15)

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Central, Inc.
MSC#17382
Aon
PO Box 1447
Lincolnshire IL 60069 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 FAX (A/C. No.): (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Old Republic Insurance Company	24147
INSURER B:		
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER							
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N	N/A		AOS				
A	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			MWXS31274524	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
				Excess WC - MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570103677315

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Stryker Corporation — MDEG License # (if applicable): _____

Physical Address: 47900 Bayside Parkway

City: Fremont — State: CA — Zip: 94536

Mailing Address (if different from physical address): Same as physical address

City: _____ — State: _____ — Zip: _____

Telephone: 408-821-1370 — Website: https://stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Carol Jane — Middle: _____ — Last: Romero

Alias(es, nicknames, name changes, etc.): Not applicable

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☑ F ☐ X

Mailing Address: [redacted] Andrea Place

City: Santa Clara — State: CA — Zip: 95051

Telephone: 408-821-1370 — Email: carol.romero@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California Polytechnic State University		1999-2005	
Address	**City**	**State**	**Zip**
1 Grand Ave	San Luis Obispo	CA	93407
Diploma/Degree obtained, if any			
BS-General Engineering w/Biomedical Engineering Concentration			

School Name		From - To (MM/YY – MM/YY)	
Hogan High School		1997 - 1999	
Address	**City**	**State**	**Zip**
850 Rosewood Ave	Vallejo	CA	94591
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/20-Present	[redacted] Andrea Place	Santa Clara	CA	95051
05/15- 1/2020	[redacted] Southview Court	San Jose	CA	95138
8/2011 - 5/2015	[redacted] East El Camino Real, Apt 122	Sunnyvale	CA	94087

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Stryker Corporation			04/18-Present	
Business Address		**City**	**State**	**Zip**
47900 Bayside Parkway		Fremont	CA	94536
Phone	**Title**		**Number of Employed Hours**	
408-821-1370	Assoc Manager, Quality		8,000+	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** Not applicable

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

09 May 24
Date

I, Carol Jane Romero, **certify that as the MDEG Administrator for**

Carol Jane Romero,

that I (initial that you have read and meet the following requirements):

1. CR Have a high school diploma or its equivalent;
2. CR Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CR Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CR Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carol Jane Romero
Print Name (First, Last)

Carol Romero
Original Signature (electronic, copies or stamps not accepted)

09 May 24
Date

Board Use Only	Date Received: 6/24/24

[redacted] Andrea Place Santa Clara, CA 95051 [redacted]

Carol Romero

WORK EXPERIENCE

Stryker Neurovascular- Associate Manager, Quality **April 2018-Present**

- Lead and facilitate the execution of surveillance and renewal audits with Notified Bodies (BSI and GMED)
- Respond to notified bodies on nonconformities and minor observations, providing corrective actions
- Manage EU MDR project and assess impact to QMS (Quality Management Systems).
  - Worked with PMS (Post Market Surveillance) group to update procedures incorporating EU MDR regulations
  - Assess and review QMS documents to determine updates to incorporate EU MDR regulations
  - Assessment of UDI and BUDI requirements and compile procedures
  - Complete GMED training to EU MDR 2017/745 Regulation

- Liaison between Quality and cross functional groups with implementing EU MDR (201/745) regulations. Collaborate with Clinical, Regulatory, Design Control, Packaging & Labelling and Operations groups to align changes with QMS documents
- Manage project to implement 2X Sterilization process for FlowGate2 products. Collaborate with design quality, manufacturing and sterilization groups to determine tasks required for project. Drive the project from planning phase to execution.

TransAortic Medical-Senior Quality Engineer **Sep 2015- March 2018**

- Lead and facilitate the successful execution of certification and surveillance audits.
- Prepare responses to regulatory audit observations. Ensure that responses are clear and comprehensive to mitigate potential for further regulatory actions.
- Ensure compliance to ISO 13485:2003/2012/2016 standard
- Compile Management Review slides and compile content for management review discussion
- Responsible for Quality Systems: CAPA's, NCMR, Complaint system (HHE), Supplier Management
- Implement UDI (Unique Device Identification) to meet FDA requirements. Implement Sidco Labeling System for compliance to FDA UDI. Coordinate validation activities and required document updates for implementation of Sidco label system.
- Supervise Document Control and ensure compliance to change management requirements
- Responsible for maintaining Equipment Calibration
- Execute updates to Instructions for Use (IFU) and Labelling to address complaint corrective actions
- Develop quality assurance specification, test method, sampling plans and related written procedures
- Coordinate Sterilization (EO Validation) for next generation Expandable Introducer Product
- Coordinate Biocompatibility Validation testing
- Set up eMDR reporting and submission of eMDR reports for adverse events
- MDV and MDR Adverse Event Reporting

Boston Scientific- Structural Heart- Senior Quality Engineer **July 2013- Sep 2015**

- Supporting operations goals for quality and reliability, continuous improvement, and problem solving. Develop, establish, and maintain quality engineering methodologies and practices, which meet BSC, customer, and regulatory requirements.
- Control manufacturing process defects by leading efforts focused on identifying primary root causes and implementing corrective and preventative actions.
- Develop and coordinate the execution and documentation of Design Validation and Verification activities to confirm design and to support regulatory submissions to Notified Bodies and FDA.
- Participate in development of product risk management tools.
- Apply sound, systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues.
- Support the determination and implementation of design controls based on risk management, customer needs and manufacturing input.
- Application of validation and statistical techniques in order to comply with associated regulatory requirements and internal standards.
- Support the Design Control System during audit activities (DEKRA audit, TGA, internal audit).
- Establish and maintain Design History File and Design Input / Output documentation (Product Specification, Component Specifications, and Prints) for In-House Tissue fixation.

- Supervise Quality Inspectors for manufacturing production group. Ensure inspectors are cross trained and allocate resources for inspection processes.
- Supervise Operations Quality Engineer I. Mentor and provide guidance regarding Nonconforming Reports, Material Review Board, engineering protocols/reports and trending production quality metrics.

Abbott Vascular- Santa Clara. Senior Quality Engineer **July 2010- July 2013**

- Develop and implement product quality plans, documents and systems by creating product specifications, risk analyses, FMEA's in conjunction with other product development team members.
- Reduce and control manufacturing process defects and incoming materials (nonconforming material) by leading efforts focused identifying primary root causes and implementing corrective and preventative actions.
- Provide direction and guidance to QE technician. Evaluate performance and assist in career development for QE technician.
- Responsible for Receiving Inspection activities in Mountain View facility.
- Design Control Quality Deliverables such as Filing and Aging studies, Proof of Concept, Process Capability
- Work closely with Regulatory function for Product Filing submissions. Submission includes: DEKRA for CE approval of ABSORB BVS Product.
- Worked with Regulatory function to support submission for Temecula IDE submission of ABSORB BVS Product.

Abbott Vascular- Santa Clara. Quality Engineer **April 2007- June 2010**

- Develop and implement product quality plans, documents and systems by creating product specifications, risk analyses, FMEA's in conjunction with other product development team members.
- Reduce and control manufacturing process defects and incoming materials (nonconforming material) by leading efforts focused identifying primary root causes and implementing corrective and preventative Actions.
- Design Control Quality Deliverables such as Filing and Aging studies,

Boston Scientific Electrophysiology, San Jose. Manufacturing Engineer **12/01/05 – March 2007**
Electrophysiology Catheter Products (Temperature Ablation Catheters & Diagnostic Catheters)

- Update manufacturing process instructions, create functional bills of materials, and trained operators.
- Manage process and procedure development to ensure operational and cost efficiency
- Design and maintain process and inspection tooling or equipment
- Coordinate and plan verification and validation activities
- Troubleshoot with new and existing products/process problems as related to design, material or manufacturing.
- Familiar with catheter based processes such as heat fusing, UV bonding, Ultrasonic Welder etc. and working with small components under a microscope.
- Communicates with vendors to support production and address issues.
- Ensure compliance with FDA, ISO, GMP, quality, safety and environmental regulations and initiatives
- Statistical analysis skills and understanding (Minitab analysis, DOE).

Boston Scientific Electrophysiology, San Jose. Quality Engineer **7/05/04 - 11/30/05**

- Coordinated the development of medical device products (catheters) to consistently produce high quality products.
- Implemented and updated quality procedures, plans and design history files.
- Drive changes in procedures, standards, test equipment and gauges to facilitate continuous improvement and to maintain quality.
- Worked cross functionally with Marketing, Regulatory, and Operations to ensure all issues are successfully resolved.
- Implement Corrective and Preventative Actions for all issues relating to quality of incoming part material, and final assembly products.
- Disposition non-conforming material (incoming material and final assembly products)

Alcon Laboratories. Co-op Engineer for Quality Engineering Dept. **1/05/04-7/05/04**
Laser Vision Correction Equipment / Technology

- Analyze failures and identify root causes.
- Develop and implement Validation Plans and Protocols.
- Perform FMEA analysis on manufacturing equipment, systems, processes, procedures, and database systems.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Stryker Corporation

Pharmacy/Wholesaler License # (if applicable): not applicable

Physical Address: 47900 Bayside Parkway

City: Fremont State: CA Zip: 94536

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 408-821-1370 Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Carol Jane Middle: Last: Romero

Alias(es, nicknames, name changes, etc.): not applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☑ F ☐ X

Mailing Addres[redacted] Andrea Place

City: Santa Clara State: CA Zip: 95051

Telephon[redacted] Email: carol.romero@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? **Not applicable**		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California Polytechnic State University		1999-2005	
Address	City	State	Zip
1 Grand Ave	San Luis Obispo	CA	94307
Diploma/Degree obtained, if any			
BS-General Engineering w/Biomedical Engineering Concentration			

School Name		From - To (MM/YY – MM/YY)	
Hogan High School		1997-1999	
Address	City	State	Zip
850 Rosewood Ave	Vallejo	CA	94591
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/20-Present	[redacted] Andrea Place	Santa Clara	CA	95051
5/2015 - 12/2019	[redacted] Southview Court	San Jose	CA	95138
06/2011-05/2015	[redacted] E. El Camino Real Apt 122	Sunnyvale	CA	94187
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Stryker Corporation				From - To (MM/YY – MM/YY):
Business Address: 47900 Bayside Parkway		City: Fremont	State: CA	Zip: 94536
Phone: 08-821-1370	Title: Assoc Manager, Quality			Number of Employed Hours: 8,000+
Description of Duties: See attached resume				
Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				
Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				
Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				
Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? **Not applicable**		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** **Not applicable**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

21 May 24
Date

I, Carol Jane Romero, **certify that as the designated representative for**

Stryker Corporation,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CR I am at least 21 years of age;
3. CR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Carol Jane Romero
Print Name (First, Last)

Carol Romero
Original Signature (electronic, copies or stamps not accepted)

11 Jun 2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carol Jane Romero

Print Name (First, Last)

Carol Romero

Original Signature (electronic, copies or stamps not accepted)

11 JUN 2024

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Alameda

I, Carol Jane Romero, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Carol Romero

Original Signature

11 Jun 2024

Date

Subscribed and Sworn to before me this _____ day of _____.

See attached jurat

Notary Public Signature

(Seal)

This Jurat is attached to the Nevada State Board of Pharmacy designated representative application signed by Carol Romero

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Alameda

Subscribed and sworn to (or affirmed) before me on this 11 day of June, 2024, by Carol Romero,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

MICHAEL SAMUEL KALTMAN
Notary Public - California
Alameda County
Commission # 2455878
My Comm. Expires Jul 30, 2027

(Seal) Signature

First Name	Last Name
Thao	Ablao
Joseph	Aboud
Shaharyar	Ali
Fatima	Alim
Shereen	Alnemri
Laura	Alvarez
Marika	Anderson
Susan	Anderson
Jennifer	Arends
Danny	Argonza
Aashish	Bapat
Mehran	Bashiri
Nina	Basurto
Peter	Baum
Jeffrey	Baxter
Angelica	Beckmann
Vardit	Benjamin
Shaily	Bhargav
Jennifer	Bishop
Karleigh	Blum
Pallavi	Bokey
Muriel	Boling
Sargon	Bourang
John	Boynton
Delwin	Bradford
Alice	Brochu
Paul	Brooke
Grace	Caasi
Lilibeth	Camins
Duong	Cao
Rosa	Cardenas
Sarena	Carniato
Jeannie	Carrion
Mikael	Cars
Shana	Castelli
Kevin	Castro Pena
Huey	Chan
Annie	Chang
Swati	Chaturvedi
Anirudh	Chaturvedi
Hancun	Chen
Ankith	Cherala
Harsh	Chheda
Rachel	Chiang
Gregory	Chin
Sharath	Chinnakavanam Sundararaj
Stella Than	Chu
Ted	Chun
Brandon	Cohen
Jennifer	Conklin
Ana	Conrado
Nicholas	Corey
Kimberly	Cortese

Darren	Coughlan
Marissa	Cucinotta
Sandy	Da Silva
Sandhya	Dammu
John	Daniel
Jimmy Duy	Dao
Stacy	Daoang
Camille	Daszynski
Stephanie	Dau
Jason	Delgadillo
Laura	Dempsey
Benjamin	Dennis
Sebastien	Dervieux
ROHAN	DESAI
Sharmila	Desai
Harish	Dixit
Payal	Dixit
My Ngoc	Do
Hanh	Doan
Hong	Doan
My	Doan
Chelsea	Douglas
Kieuhanh	DUONG
Valerie	Duvillier
Armon	Ebrahimian
WALTER	EDWARDS
May	Espena
Carlos	Estrada
Peter	Fabri
Patricia	Fagundes
Americo	Felix Raposo
Annette	Fiske
Augustine	Foley
Paul	Fong
Pearla	Fram
Deborah	Frazier
Sergey	Frenklakh
Pan Pan	Fu
Ghislain	Gackiere
ALSTON	GAINES
Randy	Gamarra
Radheeka	Gandhi
Kusuma	Gandu
Gleb	Ganin
Brent	Gerberding
Jonathan	Gibbs
NAVJEET	GILL
Susan	Gillio
Jason	Glithero
Hortencia	Gonzalez
Paul	Gordon
Sonu	Goyat
James	Graham
Danielle	Greenspan
Tsion	Hailemichael

Shazia	Hakim
Breskella	Halteh
Ronnie	Han
Matthew	Hardin
Abir	Hasnat
Siow-Hui	Hau
Ellen	Hellmoldt
Jaqueline	Hernandez
DOMINGA	HERNANDEZ
David A	Hess
Hailey	Hinkle
Hanh My	Ho
Clark	Hobson
Chin Chin	Hsueh
Kyai	Hsueh
Kathleen	Huang
Yeun Joung	Huang
Yiying	Huang
Rajeshwari	Hugar
Susan	Huser
Arzu	Inci
Marvin	Ines
Jennifer	Irwin
Pooja	Iyer
Kelly	Jabbal
Roderick	James
Mengling	Jia
Ke-Wei	Jin
Lawrence	Joaquin
Amarjit K	Johal
Karl	Johannes
Nisha	Joshi
Ricardo	Juarez Martinez
Nishi	Juthani
Michael	Kaltman
Madhuvanthi	Kandadai
Emily	Kao
Aparna	Kapur
Halil	Karabey
Mukul	Kelkar
Madalyn	Kern
Riddhi	Kharidia
Del	Kjos
Lucy	Kong
Alison	Kong-Holtzclaw
Esther	Koo
Inna	Koroleva
Johann	Krieger
Olivia	Krutz
Chantell	Kuhlmann
David	Kuwaye
Beatrice	Labrado
Danny	Lai
Stan	Lam
Virginia	Lane

Noelle	Langmack
Joshua	Lazar
Maggie	Le
Ellen	Le
Andrew	Lee
Taylor	Lee
Garvin	Leon-Yip
Sara	Leventon
Aleksandr	Leynov
Alice	Lin
Jarrett	Link
Siddharth	Loganathan
Francisco	Lomeli
Justin	Londre
Tara	Lopez
Alexa	Lopez
Phyu Phyu	Lwin
Lisa	Ly
Christina	Ma
Timothy	Macagba
Katherine	Mack
Tom	Malahom
Frederick	Mandapat
Kiran	Manickam
Andrew	Manlutac
Allison	Marley
Jennifer	Mateus
Travis	May
Lorraine	Mazzeo
Corey	McEvoy
Sean	McFerran
Megan	McGuire
Michael	McManamon
Scott	Merchel
Alyssa	Meyer
Lucia	Mokres
Soledad	Mora
Rebecca	Mora
SAMIT	MUSTAFA
Usha Sree	Musunuri
Sathy Mariappan	Nagaraj
Aditya	Nallur
Neha	Narang
Rodas	Nega
Tra	Ngo
Michael	Ngo
Walter	Nguyen
Hieu	Nguyen
Nam	Nguyen
Kim	Nguyen
Bich	Nguyen
Michael	Nguyen
Khanh	Nguyen
Hanh	Nguyen

Tan	Nguyen
Michael	Nguyen
Loan	Nguyen
ANH	NGUYEN
Michael	Nguyen
Timothy	Nguyen
Priya	Niroula
Donna	Nobida
Mark	O'Brien
Kevin	Oh
Camila	Olivato Navarro
Shakieb	Orgunwall
Daniel	Pannell
Nicolette	Panos
MICHELLE	PAREKH
Yoon	Park
Pedro	Pastoriza
Chetan	Patadiya
Radhika	Patel
Azita	Patel
Amiell	Paz
Leah	Pepe
Eric	Perkins
Thy	Pham
Kevin	Pham
Linda	Phitsamay
Mark Minh	Phung
Linda Lan	Phung
Anitha	Pissay Balakrishna
Michael	Poor
Stephen	Porter
Katherine	Prendergast
Michael	Przeslawski
Lee	Puckett
Asra	Rahman-Firer
Lokesh Kumar	Raja
Ritu	Rama
Shalini	Ramesh
Sandhya Rani	Ravula
Marjorie	Renaudin ep Robert
Monica	Reymundo
Manoj	Rodrigo
Carol	Romero
Noam	Rosenthal
William	Roskopf
Zachary	Roskopf
Hillary	Rouillard
Chiradeep	Roy
Gerald	Ryan
Jake	Sabia
Pratika	Sah
Murad	Sahawneh
Hector	Salcedo
Sandhya	Santhanaraman
Rhodora	Santos

Anthony	Sarracino
Paramvir	Sawhney
Daniel	Schaeffer
Keith	Schlotthauer
Wade	Schwan
Eskinder	Seyoum
Sameer	Shawriya
Susan	Simeon
Nirmal	Singh
Angela	Smith
Xitlalic	Soto-Sida
Jacqueline	Soviero
Michael	Spencer
Allison	Spencer
Balaji	Srinivasan
Gayathri	Srinivasan
Yi-Ping	Sun
Deepu	Suresh
Angela	Swinford
Yuki	Tan
Maneesh	Taneja
Clifford	Teoh
Nhan	To
Nhi	To
Tuyen	To
Linh	To
Stacie	Tolliver
Thoa	Tran
JACQUELINE	TRAN
TU	
Mai	Tran
Kimbang	Tran
Holly	Tran
Kevin	Tran
Soa	Tran
Chenin	Trias
Cindy	Truong
Callie	Turlington
Ashley	Twitty
Akpabio	Udo
Jane	Valentin
Michael	Vasquez
Sunaina	Vepa
Robert	Vincent
Justin	Vo
Emily	Vu
Zhen	Wallis
MARJORIE	WALSH
Yixin	Wang
Han-Wei	Wang
Arthur	Wen
Emily	White
Donna	Wilson
Teddy	Wirjadisastra
Nattaly	Withington

Cara	Wong
Nathan	Wong
DongJin	Woo
Laura	Wu
Teng	Xue
Glen	Yao
Wendy	Young
Hong	Zhu
Jill	Zolla

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,987	25 %	$ 1,848	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,189	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement, changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,108	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	$ 3,888	$ 2,841	$ 2,584	$ 2,223	$ 2,713
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	$ 3,673	$ 2,683	$ 2,281	$ 1,954	$ 2,562
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

Dollar amounts in millions except per share amounts or as otherwise specified.

4L

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Stryker Communications, Inc

Physical Address: 571 Silveron Blvd

City: Flower Mound State: TX Zip: 75028

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 469-767-4461 Website: www.stryker.com

Name of Designated Representative (DR): Matthew Kirk

Licensing Company Email: statelicensing1@stryker.com DR Email: matthew.kirk@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

04/04/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Not Applicable-no pharmaceutical products
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE
Parent Company (if any): Stryker Corporation (SYK)
Corporation Name: Stryker Communications Inc
Mailing Address: 571 Silveron Blvd
City: Flower Mound State: TX Zip: 75028
Telephone: 269-385-2600 Email: austin.ke@stryker.com
Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____
Parent Company (if any): _____
Corporation/Organization Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____
Business Name: _____
Business Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Stryker Communications, Inc

Facility Name

Matthew Kirk

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4/2/2024

Date

Board Use Only	Date Received: 6/4/24	Amount: $1000-ck 172698

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
STRYKER Communications, Inc.
571 Silveron Blvd.
Flower Mound, TX 75028
Registration Number: 2031963
FEI Number*: 3002975342
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Michael Hildoerfer
STRYKER ENDOSCOPY
5900 OPTICAL CT.
San Jose, CA 95138
Phone: 408-7542000-2664

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 05/13/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

√ verification Date 6/4/24

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "STRYKER COMMUNICATIONS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "STRYKER COMMUNICATIONS, INC." WAS INCORPORATED ON THE SIXTEENTH DAY OF DECEMBER, A.D. 2004.

Jeffrey W. Bullock, Secretary of State

3897925 8300

SR# 20241774790

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203377151

Date: 05-01-24

Officer List with Percentage Owned

	Name	Title	Role	Percent Owned
Stryker Communications, Inc.	Cedron, Andres	Officer	Officer	0%
Stryker Communications, Inc.	Pierce, J. Andrew	Officer	Officer	0%

Please note that Andres Cedron left the company unexpectedly in April 2024. A replacement for his role has yet to be made.

Stryker Communications, Inc.

Ownership List with Percent Owned

Stryker Corporation	100%

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Central, Inc.
MSC#17382
Aon
PO Box 1447
Lincolnshire IL 60069 USA

CONTACT NAME:
PHONE (A/C, No, Ext): (866) 283-7122 FAX (A/C, No.): (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Old Republic Insurance Company	24147
INSURER B:		
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$2,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$3,000,000
	OTHER						PRODUCTS - COMP/OP AGG	$3,000,000
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N	N/A		AOS				
A	If yes, describe under DESCRIPTION OF OPERATIONS below			MWXS31274524	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
				Excess WC - MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570103677315

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irk

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Stryker Communications, Inc MDEG License # (if applicable): _____

Physical Address: 571 Silveron Blvd

City: Flower Mound State: TX Zip: 75028

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 469-767-4461 Website: https://stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Matthew Middle: Robert Last: Kirk

Alias(es, nicknames, name changes, etc.): Not Applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]townbluff Drive

City: Plano State: TX Zip: 75075

Telephone: 469-767-4461 Email: matthew.kirk@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

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Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Plano Senior High School		9/97-6/01	
Address	**City**	**State**	**Zip**
2200 Independence Pkwy	Plano	TX	75075
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Collin College		1/12-10/15	
Address	**City**	**State**	**Zip**
2800 E. Spring Creek	Plano	TX	75075
Diploma/Degree obtained, if any			
Associate of Science			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/16-Present	[redacted] Townbluff Dr	Plano	TX	75075
04/11-05/16	[redacted] Preston Rd # 634	Plano	TX	75093

irk

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Stryker Communications, Inc			2013-Present	
Business Address		**City**	**State**	**Zip**
571 Silveron Blvd		Flower Mound	TX	75028
Phone	**Title**		**Number of Employed Hours**	
469-767-4461	Assoc Supervisor, Quality Assurance		20,000+	
Description of Duties				
See attached Resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

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Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** Not applicable

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

May 14, 2024
Date

Irk

I, Matthew Kirk, certify that as the MDEG Administrator for

Stryker Communications, Inc,

that I (initial that you have read and meet the following requirements):

1. MK Have a high school diploma or its equivalent;
2. MK Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MK Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MK Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Kirk
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

MAY 14, 2024
Date

Board Use Only	Date Received: 6/4/24

MATT KIRK

Plano, TX 75075 [redacted]

AREAS OF EXPERTISE

- 6 Sigma & Lean Fundamentals
- Training & Development
- E-Commerce
- Inventory Management
- Kaizen Improvement Process
- Warehouse ERP
- Team Building
- Warehouse Logistics
- Customer Service

TOP 5 STRENGTHS

Analytical | Connectedness | Individualization | Restorative | Strategic

PROFESSIONAL EXPERIENCE

STRYKER, FLOWER MOUND, TX — 2022 – Present

ASSOCIATE SUPERVISOR, QUALITY CONTROL

- Manages a team of 5 that are responsible for all incoming quality acceptance, final quality control on finished goods, calibration and preventative maintenance of all tools, and the control of non-conforming product.
- Responsible for providing guidance, delegating work assignments to direct employees, ensuring members of the team are appropriately trained, and providing coaching and mentoring to grow employees in their careers.
- Oversee the development and implementation of standards, methods and procedures for inspecting, testing and evaluating the precision, accuracy and reliability of products.
- Responsible for the hiring, training, motivating, and development of all Quality Control personnel.

STRYKER, FLOWER MOUND, TX — 2019 – 2022

QUALITY ENGINEER TECHNICIAN

- Investigate, document and disposition returned product to provide data to R&D and Quality Engineers to make product improvements, as well as document and trend failures for FDA and TUV audit readiness.
- Responsible for all Returns test fixture validations and preventative maintenance, as well as maintaining all calibrated equipment.
- Perform over 2700 quality investigations per year on 5 different product lines (Visum, Chromophare, Teletom, Operon and CORIP), with a product recovery rate of 61%.
- Implemented a cycle count program for all Returns inventories using two ERP systems (Oracle and SAP). Inventory accuracy was increased to 98%, compared to a previous 80% accuracy rate.
- Run all returns reports and compile team metrics for four QE Techs (Weekly and Monthly). This data is used to drive accountability and trend root cause scrap reduction analysis.
- Project Manager for a 1-year long initiative to rewrite the entire Returns standard operating procedure, as well as a full layout redesign of the Returns area, resulting in improved product flow and cost reductions of $5k per month.

STRYKER, FLOWER MOUND, TX — 2013 – 2019

INVENTORY CONTROL COORDINATOR

- Responsible for Stryker Communications Inventory exceeding $50M onsite components as well as multiple offsite locations for finished good products. Assisted with onboarding and training of onsite third-party logistics company to minimize customer impact.
- Work with Materials, Production and Customer Care field teams to ensure parts are available in stock and in good condition for availability in critical daily shipments.
- Helped manage multiple physical inventories in 2018 improving our daily processes and increasing our inventory accuracy from 38% in Q1 to 84% by 2019.
- Significant experience with both Oracle and SAP ERP systems. Currently a resource for IS in related system escalations and partner with business customers to resolve pertinent daily issues.
- Spent over a year in shipping department responsible for accurate picking, processing, and shipping daily orders.

THE POOL GUY, PLANO, TX — 2011 – 2012

OWNER/ OPERATOR

- Founded company specializing in the maintenance and servicing of residential pools.
- Implemented processes to attain proper licensing and accreditation.
- Developed marketing materials, including direct mail and website content. Responsible for customer acquisition, retention, and satisfaction.

LESLIE'S POOL SUPPLY, FRISCO, TX 2009 – 2011

ASSISTANT STORE MANAGER

- Managed Store front of 5 associates. Keyed manager responsible for daily bank deposits and related paperwork and transactions.
- Responsible for maximizing sales and driving business by effectively supervising and managing all team members. Implemented processes resulting in continuous quarterly increases in sales.
- Daily Activities included: Customer service; inventory control; interviewing new-hire candidates; water analysis; mechanical repairs; stocking shelves.

LOWE'S HOME IMPROVEMENT CENTER, PLANO, TX 2008 – 2009

CUSTOMER SERVICE MANAGER

- Managed Front End Operations staff of 30 associates. Responsible for weekly schedule and monthly improvement meetings to drive engagement and process improvement.
- Worked collaboratively with other departments to ensure world class customer service levels while ensure inventory was accurate and in good condition.
- Responsible for monthly payroll of over $200,000 and was effective in resolving employee disputes related to accurate accounting of hours and benefits.

EDUCATION

Associate of Science, Grad. 2015 | COLLIN COUNTY COMMUNITY COLLEGE | Plano, TX

Highschool Diploma, Grad. 2000 | PLANO SENIOR HIGH SCHOOL | Plano, TX

Natarajan_Lokram
Conner_Chris
Cress_James
Cook_Mallorie
Stull_Jeff
Henriquez_Luis
Khurmi_Lokesh
Heystek_Jeff
Rau_Hannes
Swander_Kyle
Mwendabai_Dee
Clark_Michael
Stein_Richard
Nelson_Derek
Koenigsknecht_Amand
Tirri_Jason
Abbott_Michael
O'Toole_Caitlin
Vis_Jon
Brownell_Melissa
Ruffer_Alex
Walker_Isaiah
Jakkula_Naresh
Prater_Jeremy
Kroll_Nick
Lind_Colton
Zapletal_Alex
Shivani_Deepika
Gillis_Amber
Berry_Bill
Goyal_Sudeep
Kingston_Jane
Todd_Garrett
kovach_jennifer
Wilson_Casie
Walker_Josh
Dewitt_Christopher
Dodson_June
Tom_Newton
Steven_Maloney
Applegate_Brian
Urbina_Adolfo
Brew_Wendy
Decker_Ross

Boman_Madison
Monaco_Joel
Hunt_David
Endresen_Anna
Jain _Sonal
Parenti_Michael
Aiello_Frances
Altaie_Suhaib
Azevedo_Jay
Carrera_Branden
Dodge_Sam
Elmblad_Eric
Ernst_Joel
Garcia_Dan
Garza_Angel
Gisler_Kelsey
Gudritz_Jenna
Hernandez_Edgar
Hutchinson_Justin
Lobato_Adam
Long_Bennett
Moran_Bridget
Morris_Anna
Nasouti_Kaveh
Oden_Natalie
Reid_Andrew
Schlander_Jake
Tucker_Jana
Vickers_Laura
York_Robert
McCabe_Jenna
Leesley_Haley
Wendt_Isaac
Mader_Andrew
Bengali_Sachin
Bhatia_Vinay
Boussias_Dora
Danger_Elizabeth
Dather_Roderick
DeYoung_Keith
Haynes_Preston
Hinson_Brian
Jacobs_Adam
Kelliher_Katrina

Levins_Mike
Morin_Lucie
Pennington_Paul
Radcliff_Nicole
Richtmyer_Tim
Turner_Megan
Vernon_Eryn
Longlet_Peyton
Siwik_Ewelina
Vidor_Mandy
Otto_Kendall
William Starrs
Englander_Spencer
Wilmes_Mitchell
Nathan Croutch
Quetin_Irvin
Heller_Amanda
Belvalkar_Mohan
Hill_Travis
Bustamante Jose
Rodolfo_Gonzalez
Nguyen_Huy
Boyd_Andrea
González Jimmy
Henriquez_Melissa
Abdel_Ramsey
Abernathy_Rob
Abrakata_Amajuoritse
Abrakata_Amajuoritse
Abrams_Kathy
Ackerman_Lydia
Adam_Ahmed
Adamo_Matt
Adcock_Chris
Ader_Alex
Adigun_Olabode
Alleman_Lisa
Amaradasa_Udaya
Anderson Wendt_Kayla
Andrews_Robert
Andrews_Robert
Annan_Eric
Armstrong_Jamie
Atkinson_Bessie

Baer_Ken
Baker_Ricky
Ballard_Canice
Banerjee_Sumon
Barclay_Bret
Barnes_Danielle
Barrera_Andrea
Barrera_Rick
Baxter_Robert
Beal_Sherry
Bedell_Chris
Bennett_Haley
Bentsen_Amy
Betz_Kevin
Bezverkov_Michelle
Bhute_Pravin
Bisacca_James
Blackburn_Todd
Blalock_Clyde
Blesing_Lilly
Boateng-Mensah_John
Boccoleri_Gianni
Boggs_Stacy
Bowens_Walter
Brewer_Warren
Briggs_Brandy
Briggs_Sara
Brito Sierra_Joan
Bronston_Steven
Brown_Jasmine
Brown_Johhny
Bullard_Ashley
Butler_Jaysen
Byrne_Riley
Calabrese_John
Camp_Austin
Campbell_Dustin
Campomanes_Bridget
Canteen_Jon
Cardena Luna_Miguel
Rodriguez_Katie
Carrasquillo_Kenneth
Carrillo_Jj
Carter_Se'Vaughn

Casado_Teresa
Casanova_Andres
Castillo_Maria
Cave_Emilie
Cay-Hernandez_Hector
Cerrato_Fernando
Chapman_Kevin
Chapman_Matt
Chase_David
Chi_Quynh
Chi_Quynh
Chi_Sang
Chube_Angel
Cintas_#1
Cochran_Corey
Cochran_Ellie
Coello_Angela
Coello_Berenice
Coello_Francisco
Coello_Francisco
Collins_Jill
Contreras_Fidel
Contreras_Jose
Costa_Matt
Coughennower_Josh
creek_leland
Croutch_Nate
Curtiss_Rachel
Dadyan_Golbahar
Daniel_Ju-Anna
Dastrup_Alicia
Daugherty_Michelle
DeLeon_Marysol
Diaz_Armando
Done_John
Drehs_Todd
Dunbar_Clint
Dunlap_Jahmia
Dunlap_Remicka
Duong_Tom
Durbin_David
Dusenbury_Lindsay
Dutcher_Joel
Edwards_Ashleigh

Eggemeyer_Robyn
Eguia_Nancy
Elkins_Beverly
Englander_Andrea
Estabrook_Brett
Evans_Jerome
Fadela_Francisco
Farmer_Evan
Farooqi_Saadia
Fazzio_Justin
Feigelman_Jordan
Felton_Yashica
Ferguson_Kyle
Ferrell_Kristin
Finkelstein_Eric
Flikkie_Derek
Flores_Jamie
Flores_Kathrina
Focht_Doug
Ford_Mark
Francis_Richard
Frazier_Carolyn
Freddo_Paul
Frick_Rosie
Fulcher_Todd
Garbs_Aislyn
George_Saji
Gill_Andrew
Gillespie_Chase
Giwa_Yinka
Goldey_Michael
Gonzales_Richard
Gonzalez_Jose Luis
Gonzalez_Rudy
Gonzalez Badillo_Javier
Goolsby_Mark
Gorney_Alexis
Gorzeman_Adam
Grantham_Cameron
Green_Claire
Greenlee_Brad
Smith_Emily
Guard_Security

Gutierrez_Jeremy
Gutta_Divya
Halstead_Monique
Hammer_Laromie
Haneline_Regan
Harper_Shawn
Harris_Brie
Harris_Chris
Hartl_Cassius
Harvey_Emoni
Haslinger_Jeremy
Hastings_Jodie
Hastings_Ryley
Hastings_Sean
Hatcher_Kourtney
Hathi_Manan
Hedgepeth_Tyler
Hedgepeth_Tyler
Heist_Alexia
Helmberger_Karissa
Henderson_Trevor
Hendricks_Brady
Henley_Brandon
Hereford_Eric
Hernandez_Alan
Hernandez_Matthew
Hertz_Patience
Hicks_Jordan
Hinson_Bethany
Hobbs_Xavier
Holzapfel_Mark
Hudson_Rodger
Huenefeld_Jamie
Hunt_Donal
Im_Ron
Irizarry_Felix
Jackson_Chris
James_Jennifer
James_Paul
James_Quincy
Janson_Oksana
Janusz_Robert
Januszewicz_Tommy
Jarl_Jacqueline

Jarrett_Chris
Jaylen_Lee
Jenkins_Antonio
John_George
Johns_Matt
Johnson_Isaac
Johnson_Jesse
Johnston_Priscilla
Jones_Mike
Jones_Vicki
Juarez_Leslie
Kakos_Lisa
Kalyanasundaram_Keer
Kamara_Joseph
Kanakoqui_Dania
Kariuki_Leonard
Kearney_Victoria
Kempker_Larry
Kenney_Bret
Khoja_Hanif
Kidd_Amy
Kidzus_Bryan
Kielar_Matthew
King_Chris
Kirk_Matt
Kita_Kyle
Kittelson_Lauren
Knapp_Robert
Kohler_Rachael
Kolle_Ralph
Koltz_Grace
Korenek_Audra
Koskei_Edna
Kowalski_Kevin
Krider_Rachel
Kubat_Nicole
Kuenzi_Chad
Lacy_Jordan
Lammers_Joshua
Land_Tom
Leavitt_Louis
Lee_Elijah
Lee_Jeffrey
Lee_Trung

Lee_Valerie
Leesley_Ben
Leiden_Eric
Leslie_Courtney
Levins_Michael
Liberty_Eric
Long_Joselyn
Lounavaara_Antti
Luna_Miguel
Machemehl_Bridgette
Maine_Justin
Mallaber_Doug
Malone_Damon
Manager_Chef
Mancayo_Sal
Markeson_Rebekah
Marquez_Daniel
Martin_August
Martinez_Noe
Masaviru_Henry
Mata_
Mbenza_Baka
McCarn_Gerald
Mcdonald_Stephanie
McGinnis_Jennifer
Mckay_Anthonious
McMinn_Scott
Mcpherson_Michael
Mequanent_Zion
Meyers_Parker
Middleton_Jill
Miehe_Karen
Mikula_Nick
Miller_David
Miller_David
Miller_Jesse
Mistry_Neil
Mitchell_Katie
Moncrief_Angela
Moreno_Briseida
Morris_Jamie
Morrison_Angie
Musko_John
Naik_Saijal

Nair_Ash
Navolt_Denzil
Nelson_Jana
Newton_Gail
Nguyen_Lou
Nigam_Deeksha
Noel_Ben
Odabasi_Erol
Ogunleye_Kehinde
Ogunleye_Kenny
Ogunleye_Sanmi
Ollie_Jake
Onanga_Rachel
Oney_Brian
Ortiz_German
Osborne_Corey
Pagayunan_Christina
Page_Seth
Pant_Pabin
Parsons_Craig
Patterson_Jasmine
Paz_Muli
Pecino_Adam
Pendley_Steven
Perelshteyn_Eugene
Persaud_Paul
Pham_Hung
Pike_Ilene
Ponnam_Bhavani
Potts_Richard
Prewitt_Barry
Puterbaugh_Cory
Pyo_Jason
Qattan_Yousef
Quealy_Kevin
Rabby_Dawn
Rainwater_Corrine
Ramsey_Lauren
Rand_Ryan
Ray_Pepper
Rebollar_Briza
Rees_Steven
Reid-Guerrero_Cheryl
Reillo_Martin

Rendon_Ruben
Richardson_Bruce
Richmond_Sherry
Ricthmyer_Timothy
Riehl_Leslie
Rivera_Brandy
Rivera_Hector
Rivera
Rob_Farhan
Robinson_Jair
Robinson_Lida
Rojas_Laura
Romero_Salvador
Rosales_Corine
Rose_George
Rose_Jamie
Rose_Xavier
Ross_Temeka
Rossolille_Evelyn
Rossolille_Francia
Roszak_Alex
Sagara_Summer
Saju_Eldho
Santilli_Michael
Sarmiento_Mario
Schulte_Ashley
Security_
Serviss_David
Shaik_Sankar
Shakour_Ameer
shary_zach
Shove_Cory
Simleness_Jordan
Simons_Kyle
Sladaritz_Sean
Smith_Jennifer
Smith_Sara
Snow_Tracy
Son_Christine
Soto_Jose
Stanaland_Courtney
Stanton_Richard
Stith_Ray
Stombaugh_Jodi

Stone_Georgianna
Storey_Shelly
Strein_Paul
Subedi_Bishal
Sutcliffe_Benjamin
Swearingen_Jeremiah
Tabbert_Collin
Taylor_William
Tellez_Mike
Thomas_Gaylena
Thomas_Otis
Timoszyk_Butch
Torres_Luis
Travis_John
Valdez_Charlie
Vasquez_Barbara
Velasquez_Vidal
Verhovshek_Heath
Viafora_Bob
Voska_Judy
Wagner_Kelly
Walker_Kimberly
Walker_Zach
Walsh_Wil
Walsh_Wil
Welborn_Susan
Wheeler Wilson_Tori
Whicker_
Whilden_David
White_Loy
Whitt_Brandon
Williams_Tom
Wiltshire_Rich
Worra_Kevin
Wright_Tedrick
younger_jeff
Zacharias_Jinto
Zamora_Gustavo
Zamudio_Cookie
Zigler_Pondra
Zivanic_Branka
Colaso_Sonika
Hutton_Nathan
White_Daren

Vladimir_Segura
Ruben_Flores
Mark_Malone
Marysol_Deleon
Farhan_Rob
Jesse_Crane
Nguyen_Kim
Tahella_Rose
Kayla_Divine
Salami_Femi
Pedersen_Greg
Bradley_John
Del Hierro_Paige
Richmond_Sherry
King_Melissa
Blackburn_Courtney
Worra_Kevin
Rosengren_Stuart
Hoffman_David
LeBrun_Matt
Garcia_Michael
Keller_guy
Nguyen_Vincent
Kinney_Angela
Wroble_Mike
Adelson_Mike
Gutierrez_Keila
Cuffee_Kim
Stith_Maggie
VanGalder_Tommy
Merritt_Jordan
Corbett_Matt
Young_Aaron
Church_David
Floyd_Julie
McNally_Loretta
Puterbaugh_SarahMari
Johnson_Ryan
Helmberger_Karissa
Kenco_1
Kenco_2
Kenco_3
Kenco_4
Kenco_5

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Kenco_17
Kenco_18
Kenco_19
Kenco_20
Wainz_Brett
Reillo_Martin
Brown_James
Robinson_Derrick
Strein_Paul
Chi_Sang
Pham_Lauren
Noel_Ben
Sarmiento_Mario
Garcia_Sidney
Moncayo_Sal
Castillo_Maria
Jackson_Chris
Puterbaugh_Cory
Steffan_Tom
Gonzales_Gonzalo
Halstead_Monique
Pendley_Steven
Rebollar_Briza
James_Paul
Miller_David
Crow_Lavell
Security_1
Security_2
Kenco_21
Kenco_22
Kenco_23
Kenco_24
Kenco_25

Kenco_26
Kenco_27
Pant_Pabin
Kidzus_Bryan
Smith_Brandon
ISS_1
ISS_2
ISS_3
Rabby_Dawn
Gonzales_Richard
Gorman_Edward
Smith_Joshua
Joseph_Trevor
Kim_Daniel
Shows_Kendall
Baranga_Christina
Talley_Daniella
Cichocki_Peter
Young_Traci
Fabela_Pancho
Otto_Kendall
Bhute_Pravin
Thiyagarajan_Suresh K
Kitchen_1
Kitchen_2
Lee_Jeffery
Coleman_Michael
Chavez_Edwin
Anderson_Ryan
Cunningham_Alex
Giannitti_Amanda
Loken_Brian
Bennett_Rebecca
Johnson_Jenny
Cicero_Brian
Wells_Morgan
Security_3
Security_4
Mako_1
Mako_2
Mako_3
Mako_4
Mako_5
Mako_6

Mako_7
Mako_8
Mako_9
Mako_10
Keeney_Aaron
Miller_Dylan
Thomas_Ryan
Drinkut_Matthew
Canteen_1
Mosqueda_Andy
Vaca_Juan
Clark_Josh
Munnerlyn_Kevin
Flora_AJ
Mitch Hinrichs
Montoya_Carlos
Glenn_Don
Haslinger_Jeremy
Gathuma_Maina
Anderson-
Ferrara_Giancarlo
Hoelscher_Paul
Tabbert_Collin
Patnaik_Gourish
Muli_Davies
Alapati_Satya
Kinkade_Cory
Brown_Greg
Fifer_Michelle
Santos_Daniel
Kim_Joe
Zuniga_Ali
Merza_Shawn
Soanes_David
Kordic_Karlo
Olvera_Tomas
Osorio_David
Capriolo_Ryan
Stokes_Calvin
Cintas_1
Divine_Jordan
Contractor_1 FM
Contractor_2 FM
Crawford_Sherry

Evans_Anthony
Pischke_Andrew
Castillo_Joseph
Ellis_Carey
Kenco_28
Kenco_29
Kenco_30
Kenco_31
Kenco_32
Temporary_1 FM
Wanderski_Michael
Liu_Karen
Marshall_Caitlin
Figliola_Michael
John_Dylan
Schira_Derek
ISS_4
Del Rio_Diana
Thai_Cynthia
Wolski_Lucas
Barrera_Ashley
Jamie Sarzoza
Shubham_Jaiswal
Loughlin_Steven
Craigen_Joseph
Burns_Melvin
Rodriguez_Marcel
Smith_Ron
Taylor_Quincy
Chajkowski_Curtis
Huron_Chase
Raughton_Jamie
Gill_Steve
Perdue_Austin
Gonzales_Cole
Hyde_Thomas
Cuevas_Anthony
Zunaid_Kazi
Garcia_Marco
Alligood_Ron
Hunt_Thomas
Jones_Mike
Clark_Jeremy
Edge_Dan

Meyers_Scott
Thornton_Darel
Jaramillo_Paul
All_Kris
Martinez_Isaias
Naumann_Nick
Burtchell_Michael
MacKenzie_Mack
Fahim_Mirza
Patel_Ashish
Canteen_2
Harvey_Emily
Nguyen_John
White_Loy
Maupin_Sean
Dmohowski_Eric
Heim_Brad
Storer_Dan
Senn_Andy
Warnke_Tyler
Kelly_Justin
Claussen_Danielle
Mako_11
Mako_12
Mako_13
Mako_14
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Mako_16
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Mako_18
Mako_19
Mako_20
Kenco_33
Kenco_34
Kenco_35
Kenco_36
Kenco_37
Kenco_38
Genao_Jhon
Srivaths_Nidhi
Bowers_Julia
Bowen_Sam
Johnson_Gavin
Mahfud_Hatem

Wingate_Gibb
Doyle_Marc
Dankert_Tawnya
Cadena_Devon
Sampson_Deanna
Jones_Vicki
Lynch_Shannon
Hexton_Taran
Carranza_Shelby
Del Valle_Lisa
Fabila_Yolanda
Melton_Kenedi
Admire_Charles
Holmes_Garrett
Buermeyer_Scott
Rivero_Braulio
Hanlon_Scott
Popoola_Fola
Begin-
Hernandez_Juan F
Butler_Grant
Jason_Pyo
Singh_Arjan
Brown_Kellan
Ballard_Richard
Chapman_Cale
Ledoux_Tyler
Mohamed_Rana
Bardgett_Jason
Owings_Julie
Baumgarten_Bryan
Peterson_Tyler
Berrios_Matthew
Mustain_Chuck
Contractor_3 FM
Contractor_4 FM
Cerna_Denise
Carmody_Shane
Christopher_Taylor
McCoy_Joshua
Taylor_Brandon
Hardee_Dale
Kenco_39
Kenco_40

Kenco_41
Kenco_42
Kenco_43
Kenco_44
Kenco_45
Kenco_46
Chaidez_Andrew
Flower Mound Visitor_1
Flower Mound Visitor_2
Flower Mound Visitor_3
Flower Mound Visitor_4
Flower Mound Visitor_5
Flower Mound Visitor_6
Flower Mound Visitor_7
Flower Mound Visitor_8
Flower Mound Visitor_9
Flower Mound
Flower Mound Pass_1
Flower Mound Pass_2
Flower Mound Pass_3
Flower Mound Pass_4
Flower Mound Pass_5
Lobo_Ernesto
Ethier_Denis
Roberts_Reggie
Quezada_Diego
Goodman_Mark
Kellams_Jack
Hohenstein_Zachary
Kenny_Bret
Ke_Austin
Curtis_Samantha
Baham_Robert
Krumpos_Kaden
Dempsey_Joe
Garcia_Guillermo
Contreras_Junior
Security_Guard 001
Tiffany_Traylor
Quealy_Kevin
Shahi_Kapil
McKinney_Aarolyn
Ramey_Caleigh
Biggs_Erick

Bland_Trey
Drexel_Jordan
Jobe_Lyndon
Franco-Ramirez_Saul
Engstrom_Rudy
Kitchen_3
Brian_Mann
Ellie_Cochran
Steve_Workman
Adams_Jill
Mehta_Manish
Rieger_Chris
Kandra_Mallikarjun
Patel_Sameer
Castillo_Ivan
Victor_Vimala
Ryan_Kim
Security_guard002
Mercer_Dennis
Sewell_Alex
Scott_Bowen
Tran_Andrew
Leu_Chris
Largent_Cameron
Bailey_Ben
Gruen_Michael
Harpell_Sam
Johnson_Cordaryl
Christmas_Keith
Mahamed_Usama
Demas_Devan
Raasch_David
Wuensch_Jacob
Malette_Bobby
Tarpley_Jalen
Griffin_Tony
Gonzalez_Amadaamy
Fitzgerald_Jayme
Gaur_Jivesh
Castro_Cesar
Venna_Prabhath
Justin_Fike
Royer_Dennis
Epps_Randy

Smith_Daniel
Lopez_Victor
Perez_Julian
Jung_Daniel
Harrison_Kerry
Burns_Jason
West_Jessie
Olszewski_Zach
Gladden_Anthony
Smith_Benjamin
Guzman_Jesus
Toro_Donald
Caraballo_Felix
Schilling_Tristan
Abbott_Carissa
Goel_Sager
Mobley_Breanna
Borne_Madelyn
Popour_Matt
Turnbore_Faith
Williams_Jordan
Owens_Callie
Sherry_John
Read_Matt
Lewis_Jasmine
Foley_Kaela

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of Incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,948	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,189	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,100	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	$ 3,888	$ 2,841	$ 2,584	$ 2,223	$ 2,713
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	$ 3,673	$ 2,683	$ 2,281	$ 1,954	$ 2,562
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

Dollar amounts in millions except per share amounts or as otherwise specified.

4M

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Stryker Endoscopy, a Division of Stryker Corp

Physical Address: 5900 Optical Court

City: San Jose State: CA Zip: 95138

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 408-754-2000 Website: www.stryker.com

Name of Designated Representative (DR): Andres Gonzalez

Licensing Company Email: statelicensing1@stryker.com DR Email: andres.gonzalez@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Not Applicable-no pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: MI

Parent Company (if any): N/A

Corporation Name: Stryker Corporation

Mailing Address: 1941 Stryker Way

City: Portage State: MI Zip: 49002

Telephone: 269-385-2600 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Stryker Endoscopy, a Division of Stryker Corp
Facility Name

Andres.gonzalez@stryker.com
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

April/24/2024
Date

Board Use Only	Date Received: 6/17/24	Amount: 1000 - CK - 12743

Nevada Section 2: History of Company

Qualifiers:

3: Applicant does not manufacture/distribute pharmaceuticals.

4: Applicant does not manufacture/distribute controlled substances.

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing
New Search

Back To Search Results

Establishment:
STRYKER ENDOSCOPY
5900 Optical Ct
SAN JOSE, CA 95138
Registration Number: 2936485
FEI Number*: 2936485
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Michael Hildoerfer
STRYKER ENDOSCOPY
5900 OPTICAL CT.
San Jose, CA 95138
Phone: 408-7542000-2664

Verified M.H 6/18/24

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=*&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=*&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

Page Last Updated: 05/20/2024

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Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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U.S Department of Health & Human Services

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=*&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

Stryker Corp.

Name	Role
Fletcher, Robert S.	Officer
Lobo, Kevin A.	Officer & Director
Menon, Viju S.	Officer
Pierce, J. Andrew	Officer
Stiles, Spencer S.	Officer

Name	Board of Directors
McCoy, Sherilyn	Director
Brainerd, Mary	Director
Caforio MD, Giovanni	Director
Datar PhD., Srikant	Director
Golston, Allan	Director
Silvernail, Andrew	Director
Skeete Tatum, Lisa	Director
Styker, Ronda	Director
Suri, Rajeec	Director

Name	List of Top 4 Shareholders & Percentages
The Vanguard	8.2%
Group BlackRock Inc	6.6%
John W. Brown	5.3%

Incorp State Good Standing

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

STRYKER CORPORATION

was validly incorporated on February 20 , 1946 as a Michigan DOMESTIC PROFIT CORPORATION, and said corporation is validly in existence under the laws of this state.

This certificate is issued pursuant to the provisions of 1972 PA 284 to attest to the fact that the corporation is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 1st day of May , 2024.

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24050010410

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Stryker Endoscopy, a Division of Stryker Corp.
5900 Optical Court
San Jose, CA 95138

LICENSE NUMBER: 63341
EXPIRATION DATE: 9/2/2025

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 8/31/2023

102308

Home State License

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
01/22/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Stryker Corporation & Subsidiaries 1941 Stryker Way Portage MI 49002 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N	N/A		AOS				
A	(Mandatory in NH)			MWXS31274524	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			Excess WC - MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570103677315

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Stryker Endoscopy, a Division of Stryker Corp — MDEG License # (if applicable): _____

Physical Address: 5900 Optical Court

City: San Jose — State: CA — Zip: 95138

Mailing Address (if different from physical address): Same as physical address

City: _____ — State: _____ — Zip: _____

Telephone: 787-934-4714 — Website: https://stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Andres — Middle: _____ — Last: Gonzalez

Alias(es, nicknames, name changes, etc.): Andres Gonzalez Lopez

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Addr: [redacted] Terstena Pl 206

City: Santa Clara — State: CA — Zip: 95051

Telephone: 787-934-4714 — Email: andres.gonzalez@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Jacksonville Baptist Seminary		2007-Present	
Address	**City**	**State**	**Zip**
5711 Nesconnett Blvd	Jacksonville	FL	32244
Diploma/Degree obtained, if any			
Working towards MA Degree			

School Name		From - To (MM/YY – MM/YY)	
Central Baptist College		9/2002 - 6/2006	
Address	**City**	**State**	**Zip**
1501 College Avenue	Conway	AR	72034
Diploma/Degree obtained, if any			
Bachelor's Degree-Youth Ministry			

School Name		From - To (MM/YY – MM/YY)	
Escuela Carmen Bozello de Huyke		1991 - 2001	
Address	**City**	**State**	**Zip**
Calle B,	Arroyo	PR	00714
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2/22-Present	[redacted] Rodling Dr Unit H	San Jose	CA	95138
9/11-2/22	[redacted] Terstena PL 206	Santa Clara	CA	95051
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Stryker Corp			2011-Present	
Business Address		**City**	**State**	**Zip**
5900 Optical Court		San Jose	CA	95138
Phone	**Title**		**Number of Employed Hours**	
787-934-4714	Supervisor, Quality Control		27,000+	
Description of Duties				
See attached				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

May 6/2024
Date

I, Andres Gonzalez, **certify that as the MDEG Administrator for**

Stryker Corporation,

that I (initial that you have read and meet the following requirements):

1. AG Have a high school diploma or its equivalent;
2. AG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. AG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. AG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andres Gonzalez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

May 16 2024

Date

Board Use Only	Date Received:

Andres Gonzalez

[redacted] Rodling DR Unit H E-mail: andres.gonzalez@stryker.com [redacted]

OVERVIEW

Looking to pursue a career in the administrative or operations field, or any other area where my experience and skills may be effectively applied to help reach organizational goals. I'm very good at identifying new development venues in customer service and first-time contacts.

WORK HISTORY

Supervisor, Quality Control
Stryker, San Jose, CA 2022-Present
Responsible for new production QC team. Overseeing and coordinating all final inspection activities to ensure targets/KPI's are achieved. Manage and prioritize according to production needs to meet customer requirements and ensure all quality standards are met. Develop team individuals by providing training, coaching and feedback.

- Develop, coordinate and/or implement Quality inspections activities, schedules, and methods to ensure goal attainment and ensure regulatory compliance.
- Prioritize Inspection activities based on product, equipment, material, and manpower variables
- Lead continuous improvement initiatives within the Team.
- Participated in Operational meetings, Unit Reviews, Staffing Reviews and any other presentation to management, as needed.
- Identified cost reduction opportunities as part of the day-to-day job. Also, lead a Lean Lighthouse for the Rework Process series with great results.

Associate Manufacturing Supervisor
Stryker, Arroyo, PR 2016-2021
Responsible for a high-volume production line. Overseeing and coordinating production activities to ensure targets/KPI's are achieved. Manage and prioritize production to meet customer requirements and maintain inventory levels. Develop team individuals by providing training, coaching and feedback.

- Lead a team of more than 100 associates
- Develop, coordinate and/or implement production activities, schedules and methods to ensure goal attainment and ensure regulatory compliance.
- Prioritize production schedules based on product, equipment, material and manpower variables
- Lead continuous improvement initiatives within the unit.
- Participated in Operational meetings, Unit Reviews, Staffing Reviews and any other presentation to management, as needed.
- Identified cost reduction opportunities as part of the day-to-day job. Also, lead a Lean Lighthouse for the SIPS 0211 series with great results.
- Led Efficiency initiatives obtaining a 103% efficiency for manufacturing unit which represented a 5% increment.

Manufacturing Leader
Stryker, Arroyo, PR 2014-2016
Responsible for coordination and carrying out manufacturing tasks while maintaining employee safety, compliance and engagement. Ensuring team compliance with Health and Safety policy and procedures, organizing and

resou cing the area. Ability to organize a production area based on 6S principles. Accountable for actions prom ting an environment that fosters teamwork, empowerment, personal growth and development. Assists in multi le work stations and their primary associates in the training of associates.

- Led a manufacturing team composed of 150 associates.
- Led the Irrigation 2nd Shift Q-12 Champs team, obtaining the highest manufacturing score of 4.73.
- Promoted best practice manufacturing methods and delivered products on time by allocating the right resources and skills.
- Selected as a member of the SPR Scrap Reduction Team.
- Led and recommended different initiatives for effective use of visual management as a manufacturing aid.
- Developed and executed a training plan in which all manufacturing associates reached at least a 70% in their skill matrix. Training plan was adopted for both shifts.

Line Leader
Stryk r, Arroyo, PR 2011-2014
Resp nsible for assuring the daily line production goals were met. Responsible for compliance with, safety, ergon mic and quality standards of the associates and products. Directly responsible for the adequate cross training and tation in accordance with the manufacturing skills matrix. Assist the Manufacturing Leader on any produ tion and efficiency related tasks.

- Successfully led a manufacturing team composed of 16 associates.
- Participated and helped implement one piece flow and pitch for the Fluids manufacturing unit.
- Led a waste reduction initiative for one of the unit's products that resulted in 50% change over reduction time in the manufacturing line. Later adopted in other manufacturing lines.
- Led the Fluids 2nd shift Q-12 Champs team and Wellness Program.
- Developed a plan to help train and develop associates in a new manufacturing line.

Outr ach Minister
Chur h Without Walls, Guayama, PR 2006-2008
Follo -up by making calls to first-time visitors, offered additional information regarding our organization, and how the o ganization could help them regarding their particular needs. Prepared information packets, and organized teams to insure visitors felt welcomed. Designed and developed new programs and activities geared towards

reach ng more people and promoting lasting relationships with those contacts, also kept data-base up-to-date and gener ted reports.

- Developed a retention program for new visitors
- Identified and developed a group of volunteers to help with the different retention program activities that resulted in a 15% increase in member participation and retention.

Shift upervisor
Chick fil-A, Conway, AK 2005-2006
Mana ed work schedules, assuring that the team members carried all their responsibilities in a timely manner. Maki g sure that customers were satisfied with the quality of food and service provided by our team members. Maki g daily transactions such as back deposits, cash pick-ups during the day, and generated reports, among others

- Led a total of 20 associates.
- Implemented multiple initiatives to increase customer satisfaction that resulted in a 25% reduction on customer wait time.
- Created and led the implementation of a more efficient receiving and stocking of merchandise system that increased delivery efficiency by 50% and reduced onsite inventory by 10%.
- Led the store shift operations with no safety incidents and no Health Code violations for an entire year.

EDUCATION

*15 credits approved towards an **MA*** degree — 2007
Jacksonville Baptist Seminary, Jacksonville, TX

BA - Major: Youth Ministry
Central Baptist College, Conway, AK — 2002-2006

5900 Optical Court
Gonzalez

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Stryker Endoscopy, a Division of Stryker Corp

Pharmacy/Wholesaler License # (if applicable): Not applicable

Physical Address: 5900 Optical Court

City: San Jose State: CA Zip: 95138

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 787-934-4714 Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Andres Middle: Last: Gonzalez

Alias(es, nicknames, name changes, etc.): Andres Gonzalez Lopez

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]erstena Pl 206

City: Santa Clara State: CA Zip: 95051

Telephone: 787-934-4714 Email: andres.gonzalez@stryker.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? **Not applicable**		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Jacksonville Baptist Seminary		2007 - present	
Address	**City**	**State**	**Zip**
5711 Wesconnett Blvd	Jacksonville	FL	32244
Diploma/Degree obtained, if any			
Working towards MA			

School Name		From - To (MM/YY – MM/YY)	
Central Baptist College		9/2002 - 6/2006	
Address	**City**	**State**	**Zip**
1501 College Avenue	Conway	AR	72034
Diploma/Degree obtained, if any			
Bachelor's Degree - Youth Ministry			

School Name		From - To (MM/YY – MM/YY)	
Escuela Carmen Bozello de Huyke		1991 - 2001	
Address	**City**	**State**	**Zip**
Calle B	Arroyo	Puerto Rico	00714
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2011 - 2/2022	[redacted]erstena Pl 206	Santa Clara	CA	95051
2/2022 - present	[redacted]Rodling Dr Unit H	San Jose	CA	95138
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Stryker Endoscopy, a Division of Stryker Corp			2011 - Present	
Business Address		**City**	**State**	**Zip**
5900 Optical Court		San Jose	CA	95138
Phone	**Title**		**Number of Employed Hours**	
787-934-4714	Supervisor, Quality Control		27,000+	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? Not applicable		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

June 15/2024
Date

I, Andres Gonzalez, **certify that as the designated representative for**

Stryker Endoscopy, a Division of Stryker Corp,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AGL I am at least 21 years of age;
3. AGL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AGL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AGL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AGL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AGL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Andres Gonzalez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June/5/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andres Gonzalez Lopez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date: June/5/2024

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Santa Clara

I, Andres Gonzalez Lopez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature **Date:** June/5/2024

Subscribed and Sworn to before me this 5th day of June 2024

Notary Public Signature

C. DURIO
Notary Public - California
Santa Clara County
Commission # 2445952
My Comm. Expires May 29, 2027

(Seal)

Name
Anderson_Letitia_Bates
Benscoter_Steve
Blondia_Jeanne
Carpenter_Lonny
Cartier_Michael
Conway_Kelly
Furgason_David
Kristen Gipson
Groll_Vicki
Lobo_Kevin
Natarajan_Lokram
Owen_Katherine
Poorman_Justin
Puca_Michael
Rann_Steven
Slaughter_Melinda
Strauss_Adam
Terry_Chris
Wakefield_Kyle
Zanko_Bryant
Miyasato_Kara
Belen_Erin
Austin_Scott
Crane_Jesse
Becker_Yin
Rann_Karen
Ferschweiler_Stacie
Janik_John
Anderson_Todd
Baldwin_Mitch
Behnke_Keith
Flather_Chris
Kletke_Mike
Kryszak_Kevin
Unangst_Christine
Morrow_Aaron
Powell_Jody
Trumm_Michael
Wildgen_Mike
Calderon_Jose
Paul_Anindita

Carlin_Mike
Converse_Dawn
Martinson_Dan
Tallon_David
Barnum_Steve
Andy Pierce
Yedla_Padmasree
Morse_Kara
Scannell_Tim
Finley_Megan
Kennedy_Michele
Koenigsknecht_Keith
Owens_Kylie
Goldsmith_Jacob
Marucci_Jim
Floyd_David
Scott_Geoff
Patel_Tirup
Muniz_Pedro
Latham_Lara
Moss_Tristan
Rau_Hannes
Johnson_Caroline
Walen_Jim
Taylor_Bronwen
Katy Fink
Mehta_Anita
Cassar_Jason
Broderick_Adrian
Flint_Lynne
Brown_Mike
Ketterer_Ed
Broda_Christine
King_Melissa
Corbe_Irene
Sagar_Bijoy
Muraleedharan_Bala
Sharma_Renu
Haller_John_1
Paalman_Becky
Couch_Todd
Schawe_Cindy
Vander Ploeg_Jeff
Alan Douville

Koenigsknecht_Amanda
Pellegrini_Joseph
Spencer Stiles
Ryan_Thomas
McLaughlin_Kevin
Fenton_Dan
Klaer_Ryan
Tirri_Jason
Allan_David
Savirigana_Ravi Kiran
Macino_Chris
Boehnlein_Glenn
Harrison_Matt
Eckerly_Matt
Ward_Natalie
Erickson_Stacey
Saar_Brad_M
Dudink_Niek
Raymond_Rene
Folan_Emily
Sugg_Chris
Wells_Preston
Boehrer_Courtney
Zimmerman_Sally
Kumar_Yashdeep
Braun_Shaun
Doyle_Mike
Wiselka_Matthias
Zimmer_Jon
Beckloff_Jerrod
Barry_Mike
Nestor_Eamonn
Krupinski_Sarah
Niemoth_Chuck
Hegde_Santosh
Patel_Tejas
Hergott_Nancy
Tabor_Eric
Cymbaluk_Bill
O'Brien_Mike
Pandey_Dinesh
Dick_Rachel
Llave_Alison
Mazelin_Michael

McMillan_Mike
Palladino_Anthony
Love_Diedre
Wolfenbarger_Jennifer
Regan_Denny
Beloglavec_Emil
McDowell_Matt
Beach_Jason
Arnold_Laura
Menon_Viju
Hong_Louis
McCabe_Jenna
Steinhoff_Christian
Derryberry_Fabrina_1
Nason_Allana
Alexander_Terri
Kumar_Bhupender
Ludwig_Joe
Cheung_Kevin
Sabloff_Josh
Turlapati_Venkata
Wing_Angie
Baird_Brett
Yeung_KK
Headen_Alvis
Sobb_Jeff
Turnock_April
Contractor_Contractor_Master 6
Lievois_Christopher
Steeves_Jennifer
Edwards_Brian
Ritter_Tiffany
Lopez_Jonathon
Rule_Ken
Kletzel_Joseph
Campbell_Pat
Harder_Ben
Fonseca_Adilson
Balodi_Inder
Naidoo_Asogan
Chenneerappa_Venugopal
Vallejo_Hermes
Singh_Ajay
Sharma_Ajay

Rubio_Mary Jocelyn
Wood_Robert
Morrow_Aaron
Kniola_Jordan
Kumar_Sudhir
Rob Fletcher
George_Malti
Udegbe_Omozafe
Lake_Kayleigh
Cedron_Andres
Rissman_John_Allen
Mohammad_Usman
Ryan_Keely
Tabas_Amber
Fattell_Marie
McBride_Sheila
Sardoni_Taylor
Prince_Sharma
Vishwakarma_Anil
Narayan Singh_Nirbhay
Jain_Sonal
Goyal_Sudeep
Singh _Anirudh
Makan_Karan
Hawkins_Michelle
Howard Chan
Anaya_Victor
Calvo_Sergio
Pitchai_Angu
Shahnazarian_Roger
Accornero_Lindsey
Mead_Nick
Piwowarksi_Marisa
Maron_Stefan
Kang_Paul
Bryne_Riley
Rios_Priscilla
Schmidt_Anthony
Vitaliy_Tkachenko
John_Fengler
Bailey_Art
Jorgen_Walle-Jensen
Casey_Delaat
Hannah_Haghdadi

Jongsul_Seo
Stephen_Slezic
Murray_Gavin
Randall_Lim
Andrew_Robinson
Robert_Stead
Andrew_So
Serena_Lien
Kathy_Rzeszutek
Jessie_Ng
Amy_Saari- Roth
Karena_Dela Cruz
Donna_Hohertz
Granleese_Shaun
Mitchell_Visser
Justin_Choy
Colin_Russell
Alexander_Kotler
Tom_Newton
Steven_Maloney
Richard_Ryan
Rohan_Sidhu
Frederick_Hanrahan
Thien_Quang
Vivian_Wong
Misty_Kadwell
Browne_Greg
Krishna_Kundan
Sonia_Rao
Campbell_Pat
Applegate_Brian
Hannes_Rau
Taumoepeau_James
Edwin_Chung
Rohit_Subramanian
Michele_Boulianne
Monk_Jennifer
Brew_Wendy
Decker_Ross
Kennedy_Stephanie
Lowe_Mandi
Spicehandler_Dan
Buchanan_Sarah
Dutt_Dev

Sisodia_Amrita
Harrington_Todd
Clare_MacIsaac
Tom_Shafer
Jose_Marchand
Oprzadek_Christopher
Whitt_Patrick
Suraj_Bhat
Morris_Monique
Candice_Pack
Khera_Sanjay
Zhou_Cecelia
Garceau_Patrick
Collings_John
Boman_Madison
Carrothers_Kylie
Adhikari_Anush
Quan_Emily
Collingwood_Adam
Jain _Sonal
Rapson_Katelynn
Pankaj_Sharma
Dey_Carla
Will_Edwards
Rojas_Jennifer
Jordanne Mueller
Hurley_Peyton
Parenti_Michael
'_Calli
Abad_Perla
Abdul Qader_Dana
ABM_Daniel Cabezas
ABM_Rosalva Avitia
Acevedo_James
Acevedo_Monica
Agaliotis_Peter
Agoo_Judimelle
Aguirre_Sandra
Aiello_Frances
Akiyama_Michael
Alakhramsing_Arun
Aldama_Victor
Aldaz_Alfredo
Aldaz_Eleazar

Alemi_Tara
Alfaro_April
Allen_Matthew
Allison_Heather
Altaie_Suhaib
Alvaro_Lucy
Alviedo_Jose
Amezquita_Jose
Amezquita_Ricardo
Anandakumar_Spandana
Anaya_Suzie
Anderson_Kevin
Anderson-Procter_Connor
Andrade_Mario
Andre_Marc
Anikweze_Bosa
Anisman_Noy
Appell_Matt
Aquinde_Terry
Aquino_Julieta
Arena_Anthony
Argibay_Ning
Armienta_Elycia
Arquero_Malou
Arredondo_Lorena
Arredondo_Lorena
Arzate_Maria
Asthana_Shubhangi
Athigaman_Ashwin
Atique_Wafa
Avilez_Jacob
Ayala_Gerardo
Azeem_Sundus
Azevedo_Jay
Baggett_Christina
Balaji_V
Balaram_Rukmini
Balderas_Jasmine
Balinagay_Marco
Balingit_Virginia
Bambo_Reynaldo
Baniega_Jennifer
Banna_Vishnu
Barnea_Teresa

Barragan_Camila
Batista_Michelle
Bear_Pooh
Bebla_Arbelina
Becerra_Monica
Beikmann_Aric
Benjamin_d'Andre
Bennett_Lyndon
Berding_Ali
Berneck_Sherri
Beus_Benson
Bhat_Shilpa
Bielak_Amisha
Black_Stephen
Blecher_Christopher
Boado_Germel
Boehnlein_Glenn
Bonilla_Carlos
Boopathi_Jeeva
Borge_Kevin
Bothman_Ashley
Brand_Jeremy
Bray_Roshanta
Brogan_Emily
Brooke_Tony
Brum_Mary
Buell_Brad
Bui_Hong
Burk_Robert
Burley_Brook
Bushnell_Irma
Butler_Mark
Cabral_Eden
Caldwell_Kavin
Cali_Cabdi
Calimlim_Melba
Caluya_Randy
Calvillo_Isaac
Camacho_Mitch
Campagna_Chris
Campagnacamp_Ashley
Campana_Jose
Canela_Jose A.
Canty_Yvonia

Cardenas_Rose
Cardenas_Ruben
Carey_James
Carlson_Alicia
Carrera_Branden
Carrillo_Juan
Carrion_Jeannie
Carrisales_Lettie
Casas_Jordan
Cascio_Joe
Ceccato_Erin
Celeridad_Susana
Chacko_Priya
Chairez_Norma
Chan_Wesley
Chaneva_Teodora
Chang_William
Chau_Jack
Chavan_Sanika
Chehresa_Jason
Chen_Cathy Meilan
Chene_David
Cheng_Andrew
Cheung_Yik Man (Steve)
Chhem_D-Watt
Chi_Manh
Chiron_Aurelien
Chowdhry_Shivata
Chowdhury_Ali Rashed
Clark_Brian
Clark_Caitlin
Clark_Nathan
Clark_Richard
Clarke_Bryan
Coates_Megan
Coddington_Joey
Coffeen_Jared
Compass Project_Contractor #13
Congdon_Martha
Congdon_Odilia
Conner_Chris
Connor_Reid
Consiglio_James
Contractor_Pass # 17

Contractor_Pass # 18
Contractor #1_
Contractor #10_
Contractor #11_
Contractor #12_
Contractor #13_
Contractor #2_General
Contractor #20_
Contractor #3_General
Contractor #5_
Contractor #6_General
Contractor #7_
Contractor #9
Contreras_Beverly
Copp_Josh
Cortese_Kimberly
Cortez_Jonathan
Cortez_Jose
Cory Peyton_RS Hughes
Coyer_Sean
Craig_Ian
Crispell_Jason
Crotty_Dylan
Cruz_Connie
Cruz_Guadalupe
Cruz_Resty
Cruz Manzano_Felipe
Cuevas_Christian
Cui_Cole
Cuneo_Stephen
Curran_Taylor
Czerny_Adam
Da Silva_Sandy
D'Ambrosio_Ray
Dao_Tin
Das_Biswa
Dasaraju_Manoj
Davila_Josue
Day_Kyle
De Cardenas_Lourdes
De la Cruz_Melissa
DeJesus_William
Dela Cruz_E
Delafraz_Hastee

Delaney_Amyee
Delgado_Kristen
Delin_Daniel
Deng_Wenjie
Devine_Paul
Diaz_Bertha
Dini_Nicolli
Do_Brian
Do_Jason
Do_Thuan
Dodge_Sam
Downward_Brian
Dua_Roomi
Dudek_Aleksandra
Duldulao_Zachrie
Dunn_Thomas
Duong_Jessie
Duque_Maricel
Durham_Virginia
Dzigurski_Nick
Edwards_Brian
Egbert_Ashley
Egipto_Perla
Eliceche_Carrie
Eliceche_Raul
Eliyahu_Jude
Elmblad_Eric
Elmblad_Hannah
Emerson_Gage
Emperador_Vanessa
Enrile_Mary Ann
Enriquez_Jesus
Ernst_Joel
Ernst_Morgan
Espadera_Cary
Espino_Mike
Espinoza_Esmeralda
Estacio_Francis
Estahbanaty_Shana
Estrada_Valerie
Fadel_Mo
Farkas_Joseph
Farrar_Mark
Farraro_Katie

Feingold_Ben
Felix_Alicia
Felix_Samuel
Felix_Tino
Fematt_Melina
Feng_Zhaomei
Fernandez_Juan
Figueroa_Miguel
Flom_Jim
Florence_Justin
Flores_Angelina
Flores_Brianna
Flores_Chachi
Flores_Henry
Flores_Patricia
Flores_Veronica
Foley_Andrea
Fontaine_Isabelle
Forge_Parker
Forys_Domenic
Fouts_Brian
Fouts_Brian
Fowler_Joshua
Fraga_Marlene
Frazier_Debbie
Friedland_Richard
Fuentes_Maria
Fuhr_Ted
Fuhriman_Kevin
G4S_SS
Gabriel_Michelle
Gagola_Vicki
Gaintner_Michael
Galvan_Briejett
Gandotra_Jatin
Gapuz_Eric
Garceau_Kelsey
Garcia_Alma
Garcia_Dan
Garza_Angel
Garza_Patrick
Gemmell_Sara
Gengo_Elliott
Jose George

Gerwe_Nick
Ghanati_Nina
Ghobreal_Maher
Gilman_Ryan
Giragama_Dan
Giron_Alex
Gisler_Kelsey
Gisler_Kyle
Glassford_Michael
Gloria_Raymund
Godbey_Ruth
Goddard_Paige
Godoy_Selena
Gomez_Josefina
Gomez_Leilani
Gonia_Kim
Gonzalez_Javier
Gonzalez_Nester P
Gordillo_Thomas
Greiner_Andrew
Griffith_Drew
Grose_Brandon
Guardeno_Ezequiel
Gudritz_Jenna
Guerrero_Alfredo
Guerrero_Jared
Guliani_Amit
Gundi_Mithun
Gupte_Sanika
Gutierrez_Cruz
Gutierrez_Yesenia
Habib_Usman
Hagerty_Jack
Hall_Molly
Halteh_Breskella
Hameed_Salmaan
Hamel_Andy
Hamilton_Andrew
Han_Zabrina
Hanning_Steve
Harb_Elizabeth
Haritsa_Shubhashree
Harrington_Todd
Harris_Mya

Harris_Rebecca
Hartz_Kyle
Hartz_Sarah
Hasan_Sadia
Hasan_Umar
Hawkey_Adam
Hayes_Cheryl
Haywood_Shianne
Heath_Annie
Herald_Brad
Hernandez_Aaron
Hernandez_Art
Hernandez_David
Hernandez_Edgar
Hernandez_Herlinda
Hernandez_Jeannine
Hernandez_Jess
Hernandez_Joanna
Hernandez_Pascual
Herrera_Kim
Hertel_Amanda
Hicks_Patrice
Higgins_Alaina
hill_rob
Hilldoerfer_Mike
Him_Ronno
Hinh_Huyen
Hiznay_Alexa
Hoang_Cuong
Holt_Zack
Homen_Lance
Honda_Melissa
Hondal_Kevyn
Horgan_Dr. Santiago
Hotchkiss_Jimmy
Hu_Perry
Hu_Wendy
Hui_Jerre
Hume_Courtney
Hunter_Brad
Hunter_Cole
Husain_Sarah
Hutchinson_Justin
Huynh_Eric

Hwang_Paul
Ibarra_Juan
Iverson_Carlene
Jacinto_Mildred
Jacobs_Jess
Jacobs_Jess
Jacobson_Sophie
Jafri_Rida
Janssen_Nick
Jatiram_Jeremiah
Jefferson_Ronald
Jeffries_Garrett
Jenkins_Jake
Jett_Ashley
Jila_Afshin
Jimenez_Cathleen
Jimenez_Jacob
Jin_David
Joe_Rachel
Johnson_Jeff
Jones_Barrie
Jones_Meagan
Jones_Rob
Jones_Ryan
Jones_Sam
Joshi_Harsha
Juan_Genny
Jurado_Marcos
Jurado_Steven
Justo_Rowena
Kahn_Mike
Kaiser_Bill
Kauker_Barry
Kaul_Boby
Keith_Koreen
Keithly_Glenn
Kemp_Annie
Kennedy_Ian
Kennedy_Nadia
Ketelsen_Kyle
Khan_Husnain
Khan_Malik
Khin_Mar Cho
Khu_Ramon

Kidd_Alex
Kiefer_Bryan
Kienbaum_Mary
Kim_Kwang
Kimara_Zachary
Kimura_Katy
Kinzer_Taylor
Klein_Geoff
Kling_Joshua
Kneeley_Megan
Knoell_Lauren
Kollur_Ashok
Kong_Sopheak
Kothandapani_Harish
Kozlovsky_Karen
Kramer_Allison
Krone_Jackson
Krstyen_Mark
Kumar_Rakesh
Kummareddy_Vijay
Kundu_Soumendu
Kuo_David
Kuok_Andy
Kushi_Jaymie
Ladd_Brent
LaDuca_Christine
Lagarto_Christina
Lanoue_Laurie
Lanoza_Stephanie
Lansang_Christine
Larson_Bryan
Larson_John Michael
Larson_Kimberly
Lau_Janet
Layton_Joe
Le_Cuc Thi
Le_Hung
Le_Minh
Le_My
Le_Tai
Lederer_Lindsey
Lee_Brenda
Lee_Brian
Lee_Charlie

Lee_Gordon
Lee_Michael
Lee_Robyn
Lee_Victoria
Lee_Zac
Li_Ming
Li_Wenjing
Liang_Yening
Lin_Alice
Lin_Li-Chen
Linden_Rob
Lindner_Nick
Llaban_Ian
Loi_Phong
Loney_Katie
Long_Bennett
Long_Josh
Lopes_Edson
Lopez_Jesus
Lopez_Lucio
Lopez_Pauline
Lorenzen_John
Loveless_Howard
Low_Brett
Lower_Ashley
Lu_Katherine
Lugo_Sarah
Luis_Diane
Luna_Lito
Luna_Rosa
Luong_Hoa Xuan
Luong_Ken
Luu_Huy
Luu_Tina
Ly_Andy
Ly_Linda
Ly_Ngoc
Lynch_Kimberly
Maderich_Aileen
Magana_Joseph
Mahadik_Amit
Mahadik_Kiran
Maida_Erika
Majumder_Dipayan

Maldonado_Alejandra
Malmborg_April
Mandati_Cinzia
Mander_Sukhi
Mangano_Brianna
Mangla_Ashna
Manuel_Rainier
Margaryan_Luiza
Martin_Justine
Martinez_Lynelle
Martinez_Manuel
Martorell_Danielle
Mastandrea_Mark
Matsuyama_Allen
Maulick_Steve
Mayer_Bob
Mccarroll_Kelley
McCarthy_Emmet
McCrone_Brian
McDonnell_Joseph
McGhee_Chris
McGlynn_William
McGuinness_Jane
McGuire_Jen
McKaig_Emily
McKnight_Eamonn
Mechem_Nicolette
Medina Colon_Noraliz
Mehta_Nishit
Mellits_Cara
Mendes_Edward
Mendez_Linda
Mendoza_Cecilia
Mendoza_Ramiro
Mendza_Jenipher
Menjivar_Daniel
Menon_Viju
Meraz_Art
Mercado_Dan
Mercer_Tevin
Mesa_Michael
Miceli_Rickie
Milich_Victoria
Miller_Megan

Mina_Marily
Mishra_Ajay
Mitchell_Dimitri
Mitchell_West
Mollard_Rachel
Mondala_Mary Ann
Moore_Alexis
Moore_Brandon
Mora_Rebecca
Mora_Soledad
Morales_Bersabe
Moran_Bridget
Morell_Jeff
Moreno_Jose
Moreno_Maria
Morey_Andrew
Morningstar_Callie
Morris_Anna
Muddasani_Chetan
Mujdza_Stojanka
Murdock_Matt
Murgallis_Adam
Nalvarian_Karen
Nario_Ernesto
Nasouti_Kaveh
Nava Garcia_Maria Elena
Navarro_Emmanuel
Neal_Melanie
Nebril_Danny
Negru_Catinca
Neibergall_Matthew
Ngo_Vinh
Nguyen_Andrew
Nguyen_Angie
Nguyen_Anh
Nguyen_Chinh
Nguyen_Danny
Nguyen_Danny Xuan
Nguyen_Ha
Nguyen_Hoan
Nguyen_Kaitlyn
Nguyen_Kim
Nguyen_Suong
Nguyen_Thi

Nguyen_Thuan
Nguyen_Tien Van
Nguyen_Uyen Ha
Nguyen-Khoa_Frances
Ni_Candice
Nielsen_Kristen
Nielsen_Paul
Nikami_Gary
Nojopranoto_Isa
Oakson_Sherri
O'Brien_Mark
O'Brien_Michelle
O'Connor_Aron
Oden_Natalie
O'Donoghue_Kelsey
O'Farrell_Niall
O'Grady_Mary
Olivarez_Edward
Olive_Charles
One Day_
One Day_
One Day_
One Day_
One Day_
One Day_
One Day_
One Day_
One Day_Pass
One Day_Pass
One Day_Pass
One Day_Pass
One Day_Pass # 6
Oropeza_Erica
Ortega_Roberto
Ortiz Medina_Angel
Pabla_Parveen
Padilla_Rob
Paek_Sung
Palacios_Gilda
Palacios_Joseph
Pamintuan_Darlene
Pandey_Dinesh
Pandya_Falguni
Pandya_Sudip

Pang_Simon
Pappadakis_Debbie
Paramasivan_Ramanan
Parden_Bryan
Paredes_Eddie
Parker_Annalisa
Parker_John
Parthasarathi_Krishna
Partington_Shane
Pascua_Denell
Patel_Mehul
Patel_Sujal
Pavich_Susan
Pedagat_Armando
Peku_Hatixhe
Pepe_Leah
Pequeno_Hillary
Perez_David
Perez_Elias
Perez_Ezekiel
Perez_Lia
Perez_Pedro
Perez_Ramon
Perrier_Justine
Petersen_Jennifer
Petroff_Jonathan
Petty_Cody
Pham_Jenna
Pham_Minhdao
Pham_Tiffany
Phan_Lam
Phan_Stephanie
Phillips_Jacquline
Pilgeram_Kyle
Piloto_Phillip
Pina_Cindi
Pineda_Edward
Plane_Emily
Plascencia_Leticia
Poon_Alan
Porter_James
Potelicki_Adam
Prasad_Atish
Preciado_Temo

Probst_Stephanie
Pryor_Caroline
Przeslawski_Michael
Purtell_Eric
Putney_Erin
Putney_Jayme
Quindiagan_Mike
Quintos_Jay
Radford_Mike
Ragamat_Jonathan
Ragasa_Richard
Ragasa_Sherry
Raghunath_Neha
Raguini_Wesley
Rahman_Fasi
Ramadas_Dhyuti
Ramesh_Ajay
Ramirez_Alfonso
Ramirez_Eric
Ramirez_Johnny
Rasmussen_Kara
Rauch_Karen
Realon_JP
Reardon_Michael
Rebugio_Alysia
Rebugio_Chester
Reid_Andrew
Reid_Connor
Rex_Bill
Reyes_Armando
Reyes_Davynna
Ricoh_Ricoh
Riley_Michael
Rios_Maribel
Rivera_Carlos
Rivera_Norma
Riviere_Niki
Rizvi_Samina
Roberts_Andrew
Roberts_Blake
Robertson_Jerome
Robinson_Andrew
Robinson_Robbie
Robles_Jose

Rochette_Paul
Rochi_Yrma
Rockwell_Alex
Rode_Nik
Rodriguez_Brigido
Rodriguez_Chris
Rodriguez_Jennifer
Rodriguez_Jim
Roemer_Michelle
Rohan_Greg
Rohrer_Chad
Rojas_David
Romero_Carol
Romero_Julio
Rosario_William
Rossman_Brooks
Rualizo_Julita
Rubina_Michael
Ruiz_Luis
Rupp_Ben
Russell_Anastasia
Russell_Rhonda
Ryan_Jerry
Saetern_Kane
Salazar_Crystal
Salazar_Enrique
Salinas_Martha
Salud_Heidi
Sanchez_Alberto
Sanchez_Raul
Sanfilippo_Dominick
Sankaran_Meera
Sarmiento_Betty
Sath_Lida
Sattiraju_Indu
Sawwalakhe_Prajakta
Sayama_Lynette
Sayarath_Sai
Scarpetti_Gianna
Schaeffer_Kaitlyn
Schiavon_Ashlynn
Schlander_Jake
Schmidt_Anthony
Schultz_ Bowers Stephanie

Scow_Maggie
Security_G4S
Sekar_Divya
Sellers_Calvin
Senh_Andy
Serrano_Angel
Serrano_Jose
Shah_Palak
Shahnazarian_Rodger
Sharma_Ajay
Shubham_Jaiswal
Shukla_Abhilash
Shwayder_Jamie
Siebenhaar_Branden
Siegemund_Bernd
Siler-Dearring_Jaclynn
Silva_Kristi
Silva_Stephanie
Silverman_Robert
Simmons_Jammie
Simms_Russell
Singh_Arjan
Singh_Gurteg
Singh_Manpreet
Singh_Pragyan
Sisodia_Deepak
Sliwinska_Aleks
Smith_Conrad
Smith_Matt
Sniffen_Tamara
Sodhi_Harmandip
Sokol_John
Solomon_Karl
Soriano_Shelly
Sotelo_Eric
Soto_John
Soviero_Jacqueline
Spangler_Melissa
Spears_Greysen
Stagi_Justine
Stalnaker_Hannah
Stark_Dylan
Stehlik_Mike
Steinbach_Andrew

Stoeltzing_Austin
Stoien_George
Strong_Zack
Suliguin_Jayvee
Sumner_Brent
Sun_Michelle
Supangan_Juan
Swaim_Angelica
Switzer_Nick
Takhar_Jugjot
Takimoto_Emily
Tang_Jane
Tang_John
Tapiru_Jefferson
Tapparo_Alyssa
Taranukha_Taras
Taylor_Caitlin
Taylor_Hayley
Tea_David
Tessier_Jeanne
Tessier_Jeff
Testa_Brian
Thater_Stanley
Thind_Sumeet
Thomas_Tim
Thompson_Trevor
Threadgill_Earl
Timbol_Riza Marie
Timoteo_Janet
Tisch_Connor
To_Michelle
To_Wealthy
Tokarz_Sophia
Tomar_Aparna
Tong_Dai
Tong_Dat
Tong_Jane
Torres_Lupe
Torres_Norma
Toy_Stanford
Tran_Frank
Tran_Levey
Tran_Vivian
Trivedi_Medha

Truong_Toan
Tucker_Jana
Tucker_Zach
Turpo_Fred
Tuy_Kin
Twarowski_Julie
Ulaganathan_Balakrishnan
Umayam_Gene
Uphoff_Anders
Vaideeshwara_Pradeepa
Vaidya_Aditi
Valdez_Eva
Valdivia_Robert
Varner_Michael
Vasquez_Jennie
Vasquez_Kate
Vega_Brian
Vega_Maribel
Vega_Marilou
Velasco_Katie
Velasquez_Marlen
Velazquez_Raul
Velez_Tim
Venner_Emily
Verceles_Armando
Vergara_Matt
Vertin_Philip
Veyna_Lizette
Vickers_Laura
Vinson_Jessica
Virador_Patrick
Vite_Daniel
Voisin_Sara
Vryhof_Jeremy
VU_Anna
Vu_Kim
Vu_Luan Dien
Vu_Phong
Wagner_Jessie
Wagner_Kurt
Wahl_Andrew
Walker_Francisco
Walker_Luis
Wallenstein_David

Wallis_Zhen
wanczyk_Armin
Wang_Tammy
Wasserman_Eli
Watrous_David
Weinberg_Steve
Weise_Jessica
White_Dan
White_Davin
White_Estrella
White_Leah
Williams_Bridget
Williams_Scott
Williams_Zachary
Wilson_Rick
Wiseman_Diann
Withington_Nattaly
Wood_Alyssa
Wood_Dan
Woolsey_Katya
Wylie_Erin
Wynn_Ed
Yadla_Rohini
Yanez_Rudy
Yano_Eugene
Yates_James
Yetcherla_Devi
Yewa-Michel_Pauline
Yingst_Remedios
Yip_Rae-Anne
York_Robert
Yurchak_Oleg
Zakszeski_Tiffany
Zamora_Javier
Zavala_Elena
Zendejas_Juan
Zenere_Andrea
Zerbato_Nancy
Zhang_Jennie
Zhang_Yin
Zhang_Zhang
Zimmerman_Peter
Zoerb_Martha
Zuniga_Mario

Knickerbocker_Daniel
Trevino_Patricio
Ian_Scott
Alfred_Hazel
Batista_Alexander
Batista_Alexander
Bhadra_Erika
McCabe_Jenna
Singh_Vineet
Woolford_Brady
Trinh_Duy
Aida_Marinez
Akkineni_Sairam
Gianino_Sal
Lambert_Charlie
Maynard_Michael
Pineda_Hector
Rodriguez_Fabian
Ruhany_Ryan
Sebastien_Seguy
Soeffing_Marissa
Valdez_Senaida
Lam I'll_Loi
Stewart_Chris
Osborn_Ian
Shirley_visitor 15
Shirley_Visitor 16
Satvendra Singh Sikarwar
Iti_Trishna
Jennesa Andrade
India Bery
Chase Klingaman
Pixley Paul
Matt Losquadro
Chase_Audrey
Fong_Raymond
Guest #2_One Day
Jarrett_Christopher
Khoury_Natalie
McNicholas_Deirdre Gwen
Anthony Castro Mendez
Guest Badge 17
Guest Badge 16
Guest Badge 14

Guest Badge 12
Guest Badge #17
Guest Badge # 11
Ryan Wing
Guest Badge #1
Van Galder_ Tommy
Mike Solinap
Robert Saltiban
Brett Ranard
Rudy Ayson
Carlos Quintero
Phillip Celler
Kevin Siegel
Emilie Dox
Perla Contreras
Randy Grishaber
Matt Appell
Rose Kennedy
David Florczyk
Monica Valdez
John Goulart
Axisa_Joseph
Carlin_Mike
Gendes Alonso_Sabrina
Grant_Wes
Guilfoyle_Jeanine
Kumar_Yashdeep
Leonard_John
Lilly_Judson
Marabondo_Dave
Moreau_Matt
Pennington_Paul
Peterseil_Jeremy
Robertson_Tracy
Royce_Anson
Ryan_Thomas
Sayegh_Aldo
Sugg_Chris
Todd_Erik
Verde_Susan
White_Brian
Williams_Stefan
Cohen_Robert
Hennessy_John

Panos_Michael
Pellegrini_Joseph
Ed Givens
Roberto Perez
Matt Thirionet
Joey Reyna
Caroline Alexander
Ryan Wing
Hector Pineda
Veronica Serrano
Tamjid Munir
Eusvaldo Arrequin
Jonathan Chau
Jonathan Chau
Vy Nguyen
Gotlib_Ilana
Dhruvinsinh Mahida
Callison_Tracy
Cordova_Lee
Cox_James
Dutcher_Tom
Grutkowski_Michael
Holden_Eric
Isom_Alyssa
Jay_Sunny
Olivares_Nick
Overstake_Meg
Subrahmanyam_Josh
Yearsley_Ryan
Zeh_Chris
David Salas
Ashley Manz
Otto_Kendall
Klein_Asa
Fernando Erismann
Julio Jimenez
Eric Aboytes
Caitlin Lucas
Wong_Ising
Lambert Lekettey
Justin Popnoe
Justin Popnoe
Turnock_Nicolle
Brad Barney

Graham_Bradley
Melissa Chasteen
Scherf_Steve
Lin_Keng-Tsai
Chavez_Karen
Rivas_Karen
Drew_Grace
Alkaslasi_Shon
Tabraiz_Aisha
Schlader_Erin
Khalil Tran
Stryker CEC #1
CEC Visitor Badge 8
CEC Visitor Badge 8
CEC Visitor Badge 9
Arista
Aaron De Watteville
CEC #2
CEC #2
CEC #2
CEC #2
Doby_Amy
Judy_Ho
Kaelah Hennessee
Koo Kim
Mark Stack
Oscar Gallardo-Chipres
RS Hughes
Eddie Wood
Tomas Olvera
Anis Panjwani
Cody Butler
Herga Prasad
Nathan Croutch
Jason Harris
Juanita Hernandez
Quetin_Irvin
Lauren Lester
Lauren Lester
Christine Casvccio
ALLIED SECURITY
ALLIED SECURITY
ALLIED SECURITY 2
ALLIED SECURITY #3

Joyce Refugio
Kinny Tran
Contractor # 17
Contractor #18
Contractor # 19
Contractor # 20
Arista
Allied Security
ALLIED Security
Rosemarie Christensen
Adam Jarvis
Elizabeth Guillen
Huang_Wesley
Benjamin Ly
Benjamin Ly
Neeraj Kumar
Anthony Viskovich
Rico Nelson_Denise
Karla Moreno
Cheena Chu
Chang_Diane
Ruscha_Paul
Balog_Juraj
Jobe_Karen
Savannah Hunt
Heller_Amanda
Zack Trites
Carlos Quintre
Aimee Reenfers
Ben Leesley
Stryker Contractor #22
Craig Adderley
One Day Pass #22
One Day Pass # 23
One Day Pass # 24
One Day Pass # 25
One Day Pass # 26
One Day Pass # 27
One Day Pass # 28
One Day Pass # 29
James Leonard
Larry Fischer
Bill Rees
Marcus Trujillo

Anuj Pant
Evelun Bermudez
Niskesh Gnanasekaran
Yvane Ma cean
Pam Borra
Eduardo Avredondo
Jose Perez
Everet Copado
Mike Wroble
Ben Ellis
Hill_Travis
Jean Zalog
Anthony Velasquez Juarez
Contractor Endo Badge # 26
Contractor Endo Badge # 27
Contractor Endo Badge # 28
Contractor Endo Badge # 29
Contractor Endo Badge # 30
Christine Casuccio
Andres Rosales
Alexander Scherp
Samantha Brennan
Cecilia Linares
Mike King
Alyssa Murillo
Casey Jimenez
Adrian Contreras Arc Mech
John Calucin
Eric Nguyen
Kevin_Wang
Raabe_Mark
Anthalena Gavin
Adam Rhetta
Mary Catherine Cook
Daniel Toruno
Jon Robles
Nguyen_Huy
Carolina Khouri
Conor Miller
Andres Gonzalez
Prasanna Murlidharan
Jerry Wang
Omozafe Udegbe
Muzimmil Zeeshan

Victor Truong
Ryan Biesty
Edgar Gonzalez
Hannah Sheldon
Jon Miller
Fisher_Patrick
Gage Paraiso
Julio Jimenez
Contractor Endo #31
Contractor Endo #32
Contractor Endo # 33
Contractor Endo # 34
Contractor Endo #35
Paul Glenn
Paul Glynn
Rob Bellinger
Guest Endo #1
Guest Endo #2
Guest Endo @# 3
Guest Endo #4
Contractor Endo # 36
Contractor Endo # 37
Contyractor Endo # 39
Contractor Endo # 39
Contractor Endo #40
Contractor Endo # 41
Contractor Endo #42
Endo Guest #51
Endo Guest # 52
Endo Guest #53
Endo Guest # 54
Endo Guest # 55
Karen Sumner
Katelyn Loney
Sharma_Shaili
Connor Jones
Marianna Burns
Silk_Stuart
Sudarshan Dhakal
Armstrong_Jamie
Campomanes_Bridget
Freddo_Paul
Green_Claire
Johns_Matt

Kowalski_Kevin
McMinn_Scott
Robinson_Lida
Shakour_Ameer
Zacharias_Jinto
William Maquinalez
Chynna Calayag
Andrew Davis
Joseph Romero
Ron Del Rosario
Davis_Dennis
Crotty_Kevin
Oswaldo Castillo
Shreya Gupta
Gaintner_Mike
Sumeet Dharota
Oscar Maldonado
Peyton Hurley
Veera Chinn
Oscar Maldonado
Amy Aranaz
Reid Traeger
Vanessa Grijalva
Daniel Burkhardt
Anthony Cuevas
Adelson_Mike
VanGalder_Tommy
Brandon Carr
Miguel Vasquez
Kris Sanders
Beljon_Stephanie
Grahame Butler
D'Andre Noah
Colten Craigin
Kris Gravelle
Cunningham_Alex
Bennett_Rebecca
Dennis Cabrera
Flora_AJ
Mitch Hinrichs
Anthony Cuevas
Satya Ramisetty
Shankar_Sharath
Gabriel Lobo

Santos_Daniel
Jeffrey Scott
Chad Evans
Sheila Brennan
Sheila Brennan
Phil Hocker
Guest Endo Badge #40
Guest Endo Badge #41
Guest Endo Badge #42
Guest Endo Badge #43
Guest Endo Badge # 44
Sherri Berenck
Grahame Butler
Media Room Endo #1
Media Room Endo #2
Media Room Endo #3
Endo CEC Badge # 1
Sanada_Andrea
Monica Orozco
Amir Delijani
mark soto
Jamie Sarzoza
Eddie Gutierrez
Levey Tran
vicente navarro
Stryker Endo Guest #61
Stryker Endo Guest # 62
Stryker Endo Guest # 63
Stryker Endo Guest # 64
Stryker Endo Guest # 65
Stryker Endo Guest # 66
Stryker Endo Guest # 67
Stryker Endo Guest # 68
Stryker Endo Guest # 69
Stryker Endo Guest # 70
Stryker Endo Guest # 71
Cynthia Havner
Connie Ng
Burke_Kelsey
Marina Tinajero
David Watrous
Annie Liu
Riley McMahon
Brian Ju

Praveen Sentha
Olivia Weymouth
John Nguyen
Lilly Phillips
David Dea
Petrina Picariello
Jessica Recio
Enrique Machado
Danny Du
Angelica Venegas
Ryan Luby
Qi Jiang
Alfredo Macababbad
Christina Sperry
Brandon Aprill
Security Officer
Irene Olivo
Stefan Mercer
Barry O'Neill
Media Room
Jonathan Lopez
Jennifer Vergara
Security Endo #21
Security Endo #22
Security Endo #23
Security Endo # 24
Janki Bhatt
Stryker Endo Guest #67
Shahab Teherian
Muhammad Koder
Ryan Ruhany
Juan Solorio
Zach Cline
Neha Bhongir
Abby LaComb
Sally Thurman
Drew Kostelecky
Kunj Shah
Dina Khatri
Vanessa Veto
John Hennessey
Kevin Werme
Kyle Bower

Emma Reeves
Caitlin Casey
LaCoursiere_Lori
Kevin Shull
Michelle Ortiz
Michelle Ortiz
Oscar De La Rosa Luna
Axel D Moran Pina
Oscar De la Rosa Luna
Brian Bui
Megan Pagano
White_Brian
Michelle Rodriguez
Vanessa Rodriguez
Scott MacGowan
Jorge Briones
Kimbra Rowen
Kimbra Rowen
Frank McCarthy
Jorge Briones
Craig Reeves
Estevan Campos
John Lu
Mark Martinez
Meghan Moss
Pryor_Makaila
Rosemarie Christensen
Juanita Hernandez
Stryker Endo CEC #31
Stryker Endo CEC #33
Stryker Endo CEC #34
Stryker Endo CEC # 35
Endo Stryker CEC #31
Khyati Pandya
Izzie Vidamo
Sundaragiri_Srujan
Steve_Workman
Mehta_Manish
Satyadeo Tanrakar
Frances Dioso
Alexis Giller
Jorge Briones--Vendor
Mordoh_Lara
Pat Campbell

Stephanie Mustain
Marlene Hernandez
Alfonso Carapia
Zach Polisky
Michael May
Michael May
Junko Sarah Griffith
Emily Plane
Emily Plane
Sergio Lopez
Alejandro Pantaleon
Juan Castro
Alisia Clement
David Tran
Sarah Manuel
Richard Arcangel
Christopher Hernandez
Andrew Fernandez
Andrew Fernandez
Will Sanderson
Jana Fuljer
Ryan Myers
Arturo murillo
Badge #1
Stryker Endo Badge #2
Stryker Endo Badge #3
Stryker Endo Badge #4
Stryker Endo Badge #5
Stryker Endo Badge #6
Stryker Endo Badge #7
Stryker Endo Badge #8
Stryker Endo Badge #9
Stryker Endo Badge #10
Bhuvesh Kaul
Jacob Weiss
Edgar C. Algario
Christina Black
Bill Prasad
Tina Kindrick
Dang Hoang

Francis Rivera
Hamed Khakipour
Olivia Lau
John Jimenez
Jesse Rodriguez
Tristan Villacrusis
Maria Sosa
Katherine Castillo
Marisol Alvarez
Chuck Ho
Aaron Batres
Luisa Tiuso
Luisa Tiuso

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,589	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,840	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,189	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology, spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,846	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,189	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,108	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	$ 3,888	$ 2,841	$ 2,584	$ 2,223	$ 2,713
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	$ 3,673	$ 2,683	$ 2,281	$ 1,954	$ 2,562
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

4N

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: TMJ Solutions, LLC

Physical Address: 6059 King Drive

City: Ventura State: CA Zip: 93003

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 805-258-2440 Website: www.stryker.com

Name of Designated Representative (DR): Lorena Lundeen

Licensing Company Email: statelicensing1@stryker.com DR Email: lorena.lundeen@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/11/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Not applicable - Devices only; no pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: FL

Parent Company (if any): Stryker Corporation (SYK)

Corporation Name: TMJ Solutions, LLC

Mailing Address: 6059 King Drive

City: Ventura State: CA Zip: 93003

Telephone: 269-385-2600 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

LL

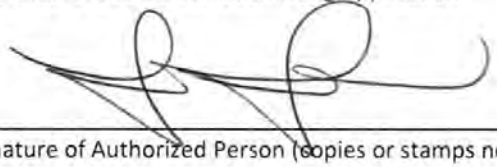
I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

TMJ Solutions, LLC

Facility Name

Lorena Lundeen

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

4/11/24

Date

Board Use Only	Date Received: 6/4/24	Amount: $1000-ck 17699

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
TMJ Solutions, LLC
Business Trade Name:
TMJ Concepts

6059 King Drive
San Buenaventura, CA 93003
Registration Number: 2031049
FEI Number*: 3001237463
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Lorena Lundeen
TMJ Solutions, LLC
6059 King Drive
Ventura, CA 93003
Phone: 1-805-6503391

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified 6/10/24 M.H

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Page Last Updated: 05/13/2024

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FDA

U.S. Food and Drug Administration
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Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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State of Florida
Department of State

I certify from the records of this office that TMJ SOLUTIONS, LLC is a limited liability company organized under the laws of the State of Florida, filed on April 1, 2021, effective December 18, 1989.

The document number of this limited liability company is L21000136285.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the First day of May, 2024

Secretary of State

Tracking Number: 0771290591CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

TMJ Solutions LLC
TMJ Concepts
6059 King Drive
Ventura , CA 93003

LICENSE NUMBER: 117251
EXPIRATION DATE: 8/4/2024

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 12/8/2022

OSP 07 102308

Officer List with Percentage Owned

	Name	Title	Role	Percent Owned
TMJ Solutions, LLC	Cedron, Andres	Officer	Officer	0%
TMJ Solutions, LLC	Pierce, J. Andrew	Officer	Officer	0%

Please note that Andres Cedron left the company unexpectedly in April 2024. A replacement for his role has yet to be made.

TMJ Solutions, LLC

Ownership List with Percent Owned

Stryker Corporation	100%

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Stryker Corporation & Subsidiaries 1941 Stryker Way Portage MI 49002 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER							
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	Y/N			AOS				
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N	N/A		MWXS31274524	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			Excess WC - MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570103677315

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG TMJ Solutions, LLC MDEG License # (if applicable) not applicable

Physical Address 6059 King Drive

City Ventura State CA Zip 93003

Mailing Address (if different from physical address) Same as physical address

City _____ State _____ Zip _____

Telephone 805-258-2440 Website https://Stryker.com

Licensing Company Email statelicensing1@stryker.com

Section 2: Personal Information

First Lorena Middle _____ Last Lundeen

Alias(es, nicknames, name changes, etc.) Lorena Lima Hernandez

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Addres[redacted] Kickapoo Drive

City Ventura State CA Zip 93001

Telephone 805-258-2440 Email lorena.lundeen@stryker.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? **Not applicable**		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Texas at El Paso		1/2005 - 12/2008	
Address	City	State	Zip
500 W University Ave	El Paso	TX	79968
Diploma/Degree obtained, if any			
Master of Business Adminstration			

School Name		From - To (MM/YY – MM/YY)	
University of Texas at El Paso		9/2000 - 5/2004	
Address	City	State	Zip
500 W University Ave	El Paso	TX	79968
Diploma/Degree obtained, if any			
Bachelor of Science, Industrial Engineering & International Manufacturing			

School Name		From - To (MM/YY – MM/YY)	
Escuela Prepatoria Federal por Cooperación 2/3 "El Chamizal"		6/1996 - 5/1999	
Address	City	State	Zip
Universidad 2255, Chamizal	Juárez, Chih.	Mexico	32310
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/14-Present	[redacted] Kickapoo Drive	Ventura	CA	93001
3/13-9/14	[redacted] Wonkel Way	Oxnard	CA	93036
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
TMJ Solutions, LLC			6/19-Present	
Business Address		**City**	**State**	**Zip**
6059 King Drive		Ventura	CA	93003
Phone	**Title**		**Number of Employed Hours**	
805-258-2440	Director, Quality-RA/QA		8,000+	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** **Not Applicable**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/14/24
Date

I, Lorena Lundeen, **certify that as the MDEG Administrator for**

TMJ Solutions, LLC,

that I (initial that you have read and meet the following requirements):

1. LL Have a high school diploma or its equivalent;
2. LL Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. LL Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. LL Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lorena Lundeen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/14/24
Date

Board Use Only	Date Received: 5/14/24

LORENA LUNDEEN
[redacted] Kickapoo Dr. Ventura, CA 93013
[redacted]

Objective To strategically lead and develop strong collaborations across divisional and regional regulatory teams to meet patient, business, regulatory needs, and requirements in a collaborative organization.

Education

INSEAD
Business Leadership Program for Executives Fontainebleau, France
Completion Date: November 2017

The University of Texas At El Paso El Paso, Texas
Master of Business Administration
Graduated: December 2008
Bachelor of Science in Industrial Engineering & International Manufacturing
Graduated: May 2004

Summary of Experience Regulatory Affairs (US and International Markets), FDA Inspections Quality & Environmental System Management (MDSAP, ISO 13485, ISO 14971, ISO 14001) New Product Development, Lean Manufacturing, Six Sigma Methodology, Post-Market Surveillance, Supplier Quality. Industries: Medical Device, Pharmaceutical Single-Use Systems, Consumer and Industrial Products.

Value Added Skill Set Access to market know-how of products compliant with all applicable local, state and federal agencies and regulatory bodies. Expertise and guidance in interpreting policies, regulatory and/or governmental regulations, and agency guidelines to assure compliance. International experience in Europe and Mexico. Biliterate English and Spanish. Cross-cultural competency. Cross-functional mentoring in hard and soft skills.

Stryker Ventura June 2019 to Present

April 2021 to Present (TMJ Solutions, LLC)
Director, Quality – RA/QA (Management Representative) Provided leadership to CMF division and associated GQO groups to support the transition to established systems. Created regulatory strategies that support the business short and mid-term. Supported cross functional alignment and deployed processes to meet regulatory compliance requirements throughout integration. Responsible to ensure consistent, quality patient-specific temporomandibular joint replacement products.

June 2019 to April 2021 (TMJ Solutions, Inc)
Director, RA/QA (Management Representative) Developed, led, and executed US and OUS regulatory strategies that demonstrated to be appropriate and effective in meeting the business needs. Executed strategies relative to market access, and global regulatory requirements. Successfully executed the site move of the class III medical device in a five-month timeframe.

Freudenberg Medical - Medical Industry October 2012 to May 2019

November 2014 to May 2019

Director of QA/RA (Management Representative) Led the implementation of Global Strategic Initiatives to improve the safety and efficacy of medical devices and products serving the medical device and pharmaceutical industries. Develop strategy for advancing the regulatory capabilities in adjacent spaces - pharmaceuticals & combination products. Responsible to ensure consistent, quality products through management and improvement of internal process controls, inspection, documentation, and supplier controls. Managed the compliance aspect of the company according to regulatory requirements, including medical device industry, biopharma, and environmental requirements.

- Led the regulatory strategy of 20+ product lines and 3 product launches covered under 13 product documentation families to satisfy transition to MDR requirements.
- Drove site-specific and global initiatives by enabling sustainable efforts towards overall improvement of Quality System effectiveness.
- Led individual and team development through training, performance review and career development plans to continuously improve results of thirty (30) person Quality team including Regulatory, Quality Assurance, Supplier Quality, Document/Change Control, and Inspection.
- Partnered with stakeholders through the value chain by enabling a cohesive understanding of the Quality goals and objectives to ensure internal and external customer requirements and satisfaction were met for 13 product family technical files and +1k components.
- Developed a strong supplier partnership by providing a closed loop feedback platform to ensure process, product, and people are in synchrony.
- Created and deployed lean initiatives into 'best in class' Quality Management System (QMS) and manufacturing practices (e.g. new product development and design transfer into production).
- Responsible for the design control system of four sites (3 US and 1 Ireland) to ensure product safety/efficacy and compliance with applicable regulations.
- Developed and deployed KPI's fostering continuous improvement.
- Obtained ISO 14001 certification by implementing the environmental system utilizing many proven QMS components previously implemented on site.
- Revised the global regulatory strategy to achieve the MDSAP certification.
- Led strategic consolidation of class IIb & IIa CE mark devices.

October 2012 to November 2014

Quality Manager (Management Representative) Restructured the Quality System to meet regulatory requirements without impacting business production throughput. Developed regulatory strategies for new product development, specifically to reduce time to market.

November 2008 to November 2011

Energizer Personal Care Schick Wilkinson Sword – Consumer Product Goods

Sr. Quality Engineer Led the Quality Initiatives of one product in development stage, one product being released to market (mass production stage) and one mature product.

- Drove design improvements through risk reduction tools.
- Created and released product specs, control plans, and testing protocols

based on design outputs/critical to quality characteristics.
- Managed Metrology and Reliability Lab.
- Key player to Global Quality Team to identify, and improve the SWS Global Quality System.
- Developed Quality Standards based on actual consumer use and on EOL expectations.

May 2007 to November 2008
GE Healthcare Monitoring Solutions - Medical Industry

Quality Engineer Ensured and improved $25M Blood Pressure Cuffs business Quality level. Lead the global process improvement of the CAPA system.

- Launched GEHC BOP CAPA Review Board.
- Leader of 2 QA Supervisors and 35 inspectors.
- Supplier CAR's champion.
- Internal CAR's champion.
- MRB leader.
- Developed process verification/validation protocols.
- Shingijutsu events key element.
- Environmental Health and Safety Ergonomics leader.
- GE Women's Network leader.

July 2006 to May 2007
CRBard - Davol Inc Medical Industry

Process Engineer Improved laparoscopy & endoscopy production floor processes.

- Championed CIP's.
- CAPA coordinator and executer.
- Fixturing Design and Implementation.
- Led Process validation: IQ, OQ, DOE and WC.
- Led line-balancing.
- Led lean project resulted in reduced inventory by 40%, labor by 30% while increasing production output by 25%.

July 2004 to January 2006
Ortronics - Homaco Telecommunications Industry

Quality Engineer Transferred production lines and suppliers.

- Released and controlled documentation to manufacture 768 finished goods.
- Led supplier validations.
- Assured specs and requirements on BPCS implementation.
- Collaboratively led engineering, materials, production & planning projects

Certification(s)/Continuing Education

Biocompatibility of Medical Devices (NAMSA)
Ethylene Oxide Sterilization for Medical Devices (AAMI)
Inclusive Leadership Program for Executives (INSEAD)
MDR (Oriel STAT A MATRIX)
MDSAP (Oriel STAT A MATRIX)
ISO 13485:2016 Lead Auditor (Oriel STAT A MATRIX)
Executive Lean Green Belt (Freudenberg)
Plastic Injection Molding (University of Massachusetts)
Six Sigma Black Belt (University of Texas)
Lean Manufacturing (University of Texas)

LORENA LUNDEEN
[redacted]Kickapoo Dr. Ventura, CA 93013
[redacted]

Objective To strategically lead and develop strong collaborations across divisional and regional regulatory teams to meet patient, business, regulatory needs, and requirements in a collaborative organization.

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July 2006 to May 2007
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Ethylene Oxide Sterilization for Medical Devices (AAMI)
Inclusive Leadership Program for Executives (INSEAD)
MDR (Oriel STAT A MATRIX)
MDSAP (Oriel STAT A MATRIX)
ISO 13485:2016 Lead Auditor (Oriel STAT A MATRIX)
Executive Lean Green Belt (Freudenberg)
Plastic Injection Molding (University of Massachusetts)
Six Sigma Black Belt (University of Texas)
Lean Manufacturing (University of Texas)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler TMJ Solutions, LLC
Pharmacy/Wholesaler License # (if applicable) _____
Physical Address 6059 King Drive
City Ventura State CA Zip 93003
Mailing Address (if different from physical address) Same as Physical address
City _____ State _____ Zip _____
Telephone 805-258-2440 Website www.stryker.com
Licensing Company Email statelicensing1@stryker.com

Section 2: Personal Information

First Lorena Middle _____ Last Lundeen
Alias(es, nicknames, name changes, etc.) Lorena Lina Hernandez
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address [redacted] Kickapoo Dr.
City Ventura State CA Zip 93001
Telephone 805-258-2440 Email lorena.lundeen@stryker.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: University of Texas at El Paso			From - To (MM/YY – MM/YY): 1/2005 – 12/2008	
Address: 500 w University Ave	City: El Paso		State: TX	Zip: 79968
Diploma/Degree obtained, if any: Master of Business Administration MBA				
School Name: University of Texas at El Paso			From - To (MM/YY – MM/YY): 9/2000 – 5/2004	
Address: 500 W. University Ave	City: El Paso		State: TX	Zip: 79968
Diploma/Degree obtained, if any: Bachelor of Science in Industrial Engineering & International Manufacturing				
School Name: Escuela Preparatoria federal por Cooperacion 2/3 El Chamizal			From - To (MM/YY – MM/YY): 6/1996 – 5/1999	
Address: Universidad 2255, Chamizal	City: Chih, Juárez		State: MX	Zip: 32310
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 10-14-today	Address: [redacted] Kickapoo Dr	City: Ventura	State: CA	Zip: 93001
From - To (MM/YY – MM/YY): 3-13-9-14	Address: [redacted] Wankel Way	City: Oxnard	State: CA	Zip: 93036
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
TMJ Solutions, LLC			6/2019-Present	
Business Address		**City**	**State**	**Zip**
6059 King Drive		Ventura	CA	93003
Phone	**Title**		**Number of Employed Hours**	
805-258-2440	Director, Quality-RA/QA		8,000+	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/16/24
Date

I, Lorena Lundeen, **certify that as the designated representative for** TMJ Solutions, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LL I am at least 21 years of age;
3. LL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lorena Lundeen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/16/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lorena Lundeen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/16/24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Ventura

I, Lorena Lundeen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/16/24

Date

Subscribed and Sworn to before me this 16 day of April 2024

Notary Public Signature

RAMESH MANWANI
COMM. # 2395758
NOTARY PUBLIC-CALIFORNIA
VENTURA COUNTY
My Commission Expires MARCH 26, 2026

(Seal)

Trisha Gill
John Raymond
Leticia Alvarez
Martha Mendoza
Lemuel Algo
Paola Nolasco
Nathaniel Martin
Fe Reynado
Aldrin Flores
Gerald Capati
Azucena (Lily) Villanueva
Jose Escamilla
Sergio Duarte
Fernando Garcia
Javier Vigil
Tony Alvarez
Adam Sepulveda
Maricela Zavala
Benjamin Wise
Nicolette Raymond
Juan Vasquez
Joseph Gill
Micah Spragg
Sandy Ignacio
Joe Garcia
Ian Barker
Diego Tapia
Naomi Romero
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Marisela Lopez
Martin Soto
Miguel Duran
Michael Puccio
John Perez
Gavin Rogers
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Roberto Aguayo
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Ashleigh Perez
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Dan Vallejo
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Marisa Solis
MICHAEL MCINERNEY
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Karlee Dominguez
Julia Bradley
Nicholas Sosa
Gage Paraiso
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Durand Porter
Lorena Lundeen
Ashritha Nara
Jackeline Cuamea

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,270	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,848	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,189	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.

COMPARISON OF CUMULATIVE FIVE YEAR TOTAL RETURN



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 169.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,103	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	$ 3,888	$ 2,841	$ 2,584	$ 2,223	$ 2,713
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	$ 3,673	$ 2,683	$ 2,281	$ 1,954	$ 2,562
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

Dollar amounts in millions except per share amounts or as otherwise specified.

40

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Tornier, Inc.

Physical Address: 10801 Nesbitt Ave. S.

City: Bloomington State: MN Zip: 55437

Mailing Address (if different from physical address): same as physical address

City: _____ State: _____ Zip: _____

Telephone: 952-426-7601 Website: www.stryker.com

Name of Designated Representative (DR): Bobby Seltz

Licensing Company Email: statelicensing1@stryker.com DR Email: bob.seltz@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others: Surgical Centers		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
	04/12/2024	AZ		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
23-0627	Arizona State Board of Pharmacy

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Stryker Sustainability Solutions, Inc., Tempe, AZ; Stryker Sustainability Solutions, Inc., Phoenix, AZ; Howmedica Osteonics Corp/Stryker Orthopaedics, Tucson, AZ

Provide explanation below:

While inspecting an additional permitted facility, The Arizona State Board of Pharmacy identified potential unpermitted activity involving a different location and opened an investigation. Applicant informed the Board that it is in the midst of a multi-year enterprise-wide project to rectify permitting oversights and voluntarily identified to the Board those locations within Arizona that Applicant believed required permitting. Applicant acknowledges that it has manufactured and sold numerous devices from and into Arizona from unpermitted locations.

Upon payment of civil penalties, the Board shall immediately grant and issue permits for all applications that Applicant shall cause to be substantively completed or resubmitted.

Original Signature (electronic, copies or stamps not accepted)

05 JUN 2024
Date

KRISTIN K. MAYES
Attorney General
Firm State Bar No. 14000

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Assistant Attorney General
State Bar No. 015072
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Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of	Case No. 23-0627
STRYKER SUSTAINABILITY SOLUTIONS, INC. (Tempe) **Applicant for Permit (M002150) as a Resident Virtual Manufacturer In the State of Arizona;** **STRYKER SUSTAINABILITY SOLUTIONS, INC. (Phoenix)** **Applicant for Permit (M002160) as a Resident Manufacturer In the State of Arizona;** **HOWMEDICA OSTEONICS, CORP. /STRYKER ORTHOPAEDICS (Tucson)** **Applicant for Permit (W003760) as a Resident Wholesaler In the State of Arizona;** **APPLICANTS**	**CONSENT AGREEMENT FOR ISSUANCE OF PERMITS AND ORDER FOR CIVIL PENALTY**

5. Applicant understands this Consent Agreement deals with a Board Complaint involving allegations of unethical conduct against Applicant. The investigation into these allegations against Applicant shall be concluded upon the Board's execution of this Consent Agreement.

6. Applicant acknowledges and agrees that the acceptance of this Consent Agreement is solely to settle this Board matter and the granting of permit applications and the resolution of unpermitted activity referenced in this Consent Agreement and does not preclude the Board from instituting other proceedings as may be appropriate now or in the future.

7. Applicant understands that, except as provided in this Consent Agreement regarding the granting of permit applications and the resolution of unpermitted activity referenced in this Consent Agreement, this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

8. Furthermore, and notwithstanding any language in this Consent Agreement, this Consent Agreement does not preclude in any way any other state agency or officer or political subdivision of this state from instituting proceedings, investigating claims, or taking legal action as may be appropriate now or in the future relating to this matter other matters concerning Applicant, including violations of Arizona's Consumer Fraud Act. Applicant acknowledges that, other than with respect to the Board, this Consent Agreement makes no representations, implied or otherwise, about the views or intended actions of any other state agency or officer or political subdivision of the state relating to this matter or other matters concerning Applicant.

9. This Consent Agreement is effective only when signed by the Executive Director. If this Consent Agreement does not become effective it is withdrawn and shall

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Stryker Sustainability Solutions, Inc. operated as a resident virtual manufacturer at two locations in the state of Arizona and Howmedica Osteonics Corp. operated as a wholesaler at one location in the state of Arizona. These three locations are not currently permitted in the state of Arizona.

3. During an inspection of a third Arizona-based Applicant location that held a permit but required a different type of permit, the Board identified potential unpermitted activity involving a different location and opened an investigation.

4. Applicant, through counsel, informed the Board that in fact, it was likely that several additional locations required permits. Applicant was already in the midst of a multi-year enterprise-wide project to rectify this oversight and voluntarily identified to the Board those locations within Arizona that Applicant believed required permitting.

5. In total, Applicant filed 28 permit applications with the Board and met with the Board on multiple occasions to discuss an efficient and orderly process to resolve all unpermitted activity at Applicant's locations that held or sought new permits.

6. Applicant acknowledges that it has manufactured and sold numerous devices from and into Arizona from unpermitted locations.

7. Applicant has 28 pending permit applications with the Board, which include administratively incomplete applications and applications that are substantively complete and ready for issuance. Three of these pending permit applications related to operations located within the State of Arizona.

CONCLUSIONS OF LAW

1. The Board asserts jurisdiction over the subject matter and over Applicant pursuant to A.R.S. § 32-1901 *et seq.*

b. **The Board shall not grant any application until it has determined through its Executive Director, that the application is substantively complete and that the Applicant has met the minimum requirements for the permit.**

c. **The Board shall not consider any unpermitted activity at any location in deciding whether an application is administratively or substantively complete and shall not deny any application or pursue any other available remedy on the basis of unpermitted activity at any location before the effective date of this Consent Agreement.**

d. For each non-resident location, the Board shall issue a non-disciplinary advisory letter for unpermitted activity.

e. Upon Applicant's execution of and compliance with the terms in this consent agreement, including payment of the amount set forth in paragraph 1 above, all matters arising out of or made in connection with this consent agreement shall be fully resolved.

3. **By entering into the Consent Agreement, Applicant waives its right to appeal. In addition, the Board may seek further remedies as permitted by statute.**

4. With respect to the approximately twenty-five (25) various permit applications pending before the Board filed by or on behalf of Stryker Corporation or its subsidiaries, the parties acknowledge that the applications are in various stages of review by Board staff. Some applications are incomplete awaiting the receipt of additional information. Other applications were administratively closed because requested information was not timely received. Applicant has stated its intention to refile those applications and have all of its facilities come into compliance with Arizona law. **The parties agree that all applications that are otherwise complete and have met the**

COPY OF THE FOREGOING E-MAILED
this 16th day of April, 2024 to:

Mark Boesen
Michael Raine
Boesen & Snow Law
8501 E. Princess Dr., Ste. 220
Scottsdale, AZ 85255
MBoesen@BSLawUSA.com
MRaine@BSLawUSA.com

COPY OF THE FOREGOING E-MAILED
this 16th day of April, 2024 to:

Jeanne Galvin Seth T. Hargraves
Assistant Attorneys General
2005 N, Central Ave, SGD/LES
Phoenix, Arizona 85004-1592
Attorney for the State
LicensingEnforcement@azag.gov

Doc #11915034

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Not Applicable-No Pharmaceutical Products
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Howmedica Osteonics Corp. and then publicly traded Stryker Corporation (SYK)
Corporation Name: Tornier, Inc.
Mailing Address: 10801 NESBITT AVE. S. BLOOMINGTON, MN 55437
City: BLOOMINGTON State: MN Zip: 55437
Telephone: 214-257-4694 Email: austin.ke@stryker.com
Contact Person Name: Austin Ke

Date of SEC Registration: 1979	SEC Registration Number: 001-13149	Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____
Parent Company (if any): _____
Corporation/Organization Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____
Business Name: _____
Business Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ Not applicable; 100% corporate owned		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** Not applicable; no CS	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** Not applicable; not required in home state	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: Not applicable; FDA registered http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. FDA registered; $25k Bond attached		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Tornier, Inc.

Facility Name

Bobby Dale Seltz

Print Name of Authorized Person Submitting Application

Bobby Seltz

Original signature of Authorized Person (copies or stamps not accepted)

05JUN2024

Date

Board Use Only	Date Received: 6/17/24	Amount: 1000-CK-12748

Nevada Section 2: History of Company

Qualifiers:

3: Applicant does not manufacture/distribute pharmaceuticals.

4: Applicant does not manufacture/distribute controlled substances.

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
TORNIER, INC.
10801 Nesbitt Avenue South
Bloomington, MN 55437
Registration Number: 1649390
FEI Number*: 3000718467
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP.[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Jeanine H Redden
1023 Cherry Road
Memphis, TN 38117
Phone: 1-901-8674522

Verified M.H 6/18/24

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryNar
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Page Last Updated: 04/22/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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Officer List with Percentage Owned

	Name	Title	Role	Percent Owned
Tornier, Inc.	Stiles, Spencer S.	Officer	Officer	0%
Tornier, Inc.	Ke, Austin	Assistant Secretary	Officer	0%

Tornier, Inc.

Ownership List with Percent Owned

Howmedica Osteonics Corp.	100%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BIOMIMETIC THERAPEUTICS USA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BIOMIMETIC THERAPEUTICS USA, INC." WAS INCORPORATED ON THE FIFTEENTH DAY OF MARCH, A.D. 2011.

Jeffrey W. Bullock, Secretary of State

4954282 8300

SR# 20241984952

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203440858

Date: 05-09-24

MINNESOTA
BOARD OF PHARMACY

Protecting the Public Since 1885 | pharmacy.board@state.mn.us
335 Randolph Ave., Suite 230 | St. Paul, MN 55102

Sent via email:

December 15, 2021

Dear

This letter is in response to your question regarding distribution of medical devices.

The Board does not license or register companies that exclusively manufacture, distribute, supply or sell medical devices or supplies. If a company that handles medical devices or supplies also manufactures or distributes drugs, it must be licensed as a drug manufacturer or drug wholesaler. Exception is if the drug is coated on or embedded in the device (e.g. drug-coated stents) and the resultant product is approved by the FDA as a device, the company does not have to be licensed as a manufacturer or wholesale distributor.

Sincerely,

Pharmacy
Surveyor

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
01/22/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Central, Inc.
MSC#17382
Aon
PO Box 1447
Lincolnshire IL 60069 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Old Republic Insurance Company	24147
INSURER B:		
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Phys Dmge-Self Insd							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324 AOS	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N	N/A		MWXS31274524 Excess WC - MI	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			SIR applies per policy terms & conditions			E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570103677315

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Tornier, Inc. MDEG License # (if applicable): Applied for

Physical Address: 10801 Nesbitt Ave. S.

City: Bloomington State: MN Zip: 55437

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 952-426-7601 Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Bobby Middle: Dale Last: Seltz

Alias(es, nicknames, name changes, etc.): Not applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 10801 Nesbitt Ave. S.

City: Bloomington State: MN Zip: 55437

Telephone: 612-254-4847 Email: bob.seltz@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Saint Mary's University of MN			01/07-01/09	
Address		City	State	Zip
700 Terrace Heights		Winona	MN	55987
Diploma/Degree obtained, if any				
BS Industrial Technology				
School Name			From - To (MM/YY – MM/YY)	
Mayer Lutheran High School			1992 - 1996	
Address		City	State	Zip
306 7th St NE		Mayer	MN	55360
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/12 - Current	[redacted]Quail Run	Waconia	MN	55387
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Tornier, Inc.			01/16 - Current	
Business Address		**City**	**State**	**Zip**
10801 Nesbitt Ave. S.		Bloomington	MN	55437
Phone	**Title**		**Number of Employed Hours**	
952-426-7601	Sr Quality Manager		12,000	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Zimmer Biomet			01/98-12/15	
Business Address		**City**	**State**	**Zip**
7375 Bush Lake Rd		Edina	MN	55439
Phone	**Title**		**Number of Employed Hours**	
574 - 267 - 6639	See resume		12,000+	
Description of Duties				
See resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2005	2006	MN	Chaska	Carver County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Not applicable		Carver County		
Reason/Charge				
4th Degree DWI - misdemeanor				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Bobby Dale Seltz			Not applicable	
Name of Business/Industry/Entity				
Not applicable				

Provide explanation below:

Not applicable

Original Signature (electronic, copies or stamps not accepted)

05 JUN 2024
Date

I, Bobby Dale Seltz, **certify that as the MDEG Administrator for**

Tornier, Inc.,

that I (initial that you have read and meet the following requirements):

1. BS Have a high school diploma or its equivalent;
2. BS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. BS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. BS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bobby Dale Seltz
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05JUN2024
Date

Board Use Only	Date Received:

Bobby D. Seltz

[redacted] Quail Run, Waconia, MN 55387 – [redacted]

Summary

Results-driven, skilled professional and leader focused on achieving success and increased productivity through improvements in quality and operations.

Highlights

- Procedure and process development
- CAPA and NCE
- Calibration and preventative maintenance
- Alignment, harmonization, integration, KPI's
- Leadership and team building
- Troubleshooting and problem solving
- Root cause analysis
- Customer service-focused

Accomplishments

- Established effective processes and procedures for field actions, product obsolescence and product expirations.
- Reduced closure time for non-conformance events and complaint intakes.
- Maintained appropriate and accurate inventory levels along with reduced inspection time to reduce or eliminate backorders.
- Overhauled temperature monitoring program (including cold storage) to be compliant which resulted in lower annual cost.
- Consistently met project timelines and milestones for assigned tasks including integration activities.
- Proven leader to ensure compliancy, cost reduction, standardize KPI's, collaboration and alignment.

Experience

STRYKER

Senior Manager, Quality Assurance – Site Lead November 2020 to Current

- Site leadership for Quality Control, Calibration/ Metrology, Human Tissue, Quality Engineering and Supplier Quality.
- Coordinate leadership for site level integration activities.
- CAPA and NC governance.
- Quality System Management Representative
- Supplier management and coordination for Quality Operations.
- Collaborate and drive continuous improvement of key performance indicators to reduce cost.
- Process improvements to reduce escapes, CAPA/NC timeliness, inspection reduction, QMS, supplier compliancy and issue monitoring.

Senior Manager, Global Quality Operations and Distribution Quality (Wright Medical) February 2018 to November 2020

- Multi-site leadership of the Quality Control, Calibration/ Metrology and Distribution Quality departments and processes.
- Coordinated leadership of Global Environmental Monitoring program including Endotoxin Laboratory and processes.
- Global harmonization of quality processes and software programs.
- Support of integration activities for Quality and Distribution processes.
- Distribution Quality leadership for CAPA's, NCE's, processes and audits.

Quality Operations Manager (Wright Medical) January 2016 to February 2018

- Perform and manage quality activities, such as inspection, document audits, non-conformances, CAPA's and customer complaints.
- Responsible for the documentation of all products and processes related to Quality Assurance and Distribution Center.
- Lead and implemented process improvement activities (5S, Lean manufacturing techniques, GDP).
- Maintain of decontamination area and water system for compliancy.

ZIMMER BIOMET

Senior Manufacturing Engineer (New Product Development) November 2013 to December 2015
Senior Process Engineering Lead March 2008 to November 2013
Manufacturing Engineer (Post Market) March 2004 to March 2008
Calibration Technician & Quality Technician April 1998 to March 2004

Key achievements:

- Increased responsibilities throughout tenure
- Process improvements
- Integration experience
- Quality processes including CAPA, NCE and complaints
- Manufacturing, Operations and Quality
- Cost reductions

Education and Certifications

Saint Mary's University of Minnesota
Bachelor of Science: Industrial Technology: 2009
Minneapolis, MN

Ridgewater College
Program Studied: Metrology: 1996-1998
Hutchinson, MN

American Society for Quality
CMI, CQT
Carlson School of Management

Operational Excellence (Lean & Six Sigma): 2010
Minneapolis, MN

Minnesota Fire Service Certification Board
Fire Fighter I & II: 2001, 2011 (current), **HazMat Operations: 2011** (current)

Emergency Medical Services Regulatory Board
Emergency Medical Responder (EMR): 2011 (current)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Tornier, Inc.

Pharmacy/Wholesaler License # (if applicable): Not applicable - applied for

Physical Address: 10801 Nesbitt Ave. S.

City: Bloomington State: MN Zip: 55437

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 952-426-7601 Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Bobby Middle: Dale Last: Seltz

Alias(es, nicknames, name changes, etc.): Not applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 10801 Nesbitt Ave. S.

City: Bloomington State: MN Zip: 55437

Telephone: 612-254-4847 Email: bob.seltz@stryker.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Saint Mary's University of MN		01/07 - 01/09	
Address	**City**	**State**	**Zip**
700 Terrace Heights	Winona	MN	55987
Diploma/Degree obtained, if any			
BS Industrial Technology			

School Name		From - To (MM/YY – MM/YY)	
Mayer Lutheran High School		1992 - 1996	
Address	**City**	**State**	**Zip**
306 7th St NE	Mayer	MN	55360
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/12 - Current	[redacted] Quail Run	Waconia	MN	55387
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Tornier, Inc.			01/16 - Current
Business Address	**City**	**State**	**Zip**
10801 Nesbitt Ave. S.	Bloomington	MN	55437
Phone	**Title**	**Number of Employed Hours**	
952-426-7601	Sr Quality Manager	12,000	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Zimmer Biomet			01/98-12/15
Business Address	**City**	**State**	**Zip**
7375 Bush Lake Rd	Edina	MN	55439
Phone	**Title**	**Number of Employed Hours**	
574-267-6639	See attached resume	12,000 +	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? Not applicable		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Bobby Dale Seltz, **certify that as the designated representative for**

Tornier, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BS I am at least 21 years of age;
3. BS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Bobby Dale Seltz

Print Name (First, Last)

BSeltz

Original Signature (electronic, copies or stamps not accepted)

05 Jun 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bobby Dale Seltz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 05JUN2024

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Hennepin

I, Bobby Dale Seltz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 07JUN2024

Subscribed and Sworn to before me this 7 day of June 2024

Notary Public Signature

COLEEN H JUNTUNEN
NOTARY PUBLIC
MINNESOTA
My Commission Expires 01/31/2028

(Seal)

Tornier Employee List

CONFIDENTIAL

First Name	Last Name	Worker Type	Location
Russell	Miller	Employee	Minnesota, Bloomington
Timothy	Foss	Employee	Minnesota, Bloomington
William	Kuester	Employee	Minnesota, Bloomington
Jeffrey	Payment	Employee	Minnesota, Bloomington
Chad	Litke	Employee	Minnesota, Bloomington
Jack	Langer	Employee	Minnesota, Bloomington
Erik	Porter	Employee	Minnesota, Bloomington
Theresa	Frisk	Employee	Minnesota, Bloomington
Peter	Chirpich	Employee	Minnesota, Bloomington
Daniel	Drollinger	Employee	Minnesota, Bloomington
Audrey	Wright	Employee	Minnesota, Bloomington
Cynthia	Ness	Employee	Minnesota, Bloomington
Blake	Beekmann	Employee	Minnesota, Bloomington
Gina	Link	Employee	Minnesota, Bloomington
Bruce	Morgan	Employee	Minnesota, Bloomington
Cherry	Fudge	Employee	Minnesota, Bloomington
Vong	Vue	Employee	Minnesota, Bloomington
Leon	Buboltz	Employee	Minnesota, Bloomington
Sandy	Yong	Employee	Minnesota, Bloomington
Coleen	Juntunen	Employee	Minnesota, Bloomington
Eric	Skarphol	Employee	Minnesota, Bloomington
Baophann	Chakrathouk	Employee	Minnesota, Bloomington
Joshua	Welch	Employee	Minnesota, Bloomington
Matthew	Rushin	Employee	Minnesota, Bloomington
Beth	Thorman	Employee	Minnesota, Bloomington
James	Turner	Employee	Minnesota, Bloomington
Vashawn	Weldon	Employee	Minnesota, Bloomington
Amine	Tekle	Employee	Minnesota, Bloomington
Ketmany	Siphaengphet	Employee	Minnesota, Bloomington
Emily	Wise	Employee	Minnesota, Bloomington
Kyle	Scheible	Employee	Minnesota, Bloomington
Paul	Ross	Employee	Minnesota, Bloomington
Renee	Stoffel	Employee	Minnesota, Bloomington
Darren	Brown	Employee	Minnesota, Bloomington
Sambath	Prum	Employee	Minnesota, Bloomington
Pa-Ja	Xiong	Employee	Minnesota, Bloomington
Bobby	Seltz	Employee	Minnesota, Bloomington
Danica	Lemieux	Employee	Minnesota, Bloomington
Dawn	Runge	Employee	Minnesota, Bloomington
Alana	House	Employee	Minnesota, Bloomington

Paul	Feng	Employee	Minnesota, Bloomington
Ann	Fitzpatrick	Employee	Minnesota, Bloomington
You	Yang	Employee	Minnesota, Bloomington
Samson	Tamire	Employee	Minnesota, Bloomington
Jack	Ryan	Employee	Minnesota, Bloomington
Nancy	Wilson	Employee	Minnesota, Bloomington
Nicole	Prokes	Employee	Minnesota, Bloomington
Timothy	Stone	Employee	Minnesota, Bloomington
Gabrielle	Schnellman	Employee	Minnesota, Bloomington
Stefanie	Tarara	Employee	Minnesota, Bloomington
Jonathan	Winkleski	Employee	Minnesota, Bloomington
Mary	Mattson	Employee	Minnesota, Bloomington
Blake	Uecker	Employee	Minnesota, Bloomington
Corey	Thompson	Employee	Minnesota, Bloomington
Cody	Kairis	Employee	Minnesota, Bloomington
Nichol	Bachand	Employee	Minnesota, Bloomington
Paul	Florin	Employee	Minnesota, Bloomington
LISA	STAHL	Employee	Minnesota, Bloomington
Andrew	Beberg	Employee	Minnesota, Bloomington
Kasey	Gadient	Employee	Minnesota, Bloomington
Mauro	Zampa	Employee	Minnesota, Bloomington
Ryan	Current	Employee	Minnesota, Bloomington
Lucas	Brunner	Employee	Minnesota, Bloomington
Dalee	Lor	Employee	Minnesota, Bloomington
Faith	Katei	Employee	Minnesota, Bloomington
Kenneth	Conn	Employee	Minnesota, Bloomington
Nicholas	Waska	Employee	Minnesota, Bloomington
Kristina	McQueen	Employee	Minnesota, Bloomington
Katie	Peer	Employee	Minnesota, Bloomington
Michael	Song	Employee	Minnesota, Bloomington
Ntsang	Anye	Employee	Minnesota, Bloomington
Shari	Mathewson	Employee	Minnesota, Bloomington
Gage	Garner	Employee	Minnesota, Bloomington
Pa	Lee	Employee	Minnesota, Bloomington
Kelly	Austin	Employee	Minnesota, Bloomington
Austin	Gilyard	Employee	Minnesota, Bloomington
Megan	Olmscheid	Employee	Minnesota, Bloomington
Sarah	Peiffer	Employee	Minnesota, Bloomington
Sydney	Dobbs	Employee	Minnesota, Bloomington
Jackline	Nyamagwa	Employee	Minnesota, Bloomington
Nina	Mundschenk	Employee	Minnesota, Bloomington

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,589	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,416	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.69	$ 169.51	$ 173.00

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

4P

M/00960

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler	* If making a change, provide current license number:	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Welch Allyn, Inc.

Physical Address: 4341 State Street Road

City: Skaneateles Falls State: New York Zip: 13153

Mailing Address (if different from physical address): 7000 Cardinal Pl, Attn: QRA

City: Dublin State: OH Zip: 43017

Telephone: 315-685-4602 Website: www.hillrom.com

Name of Designated Representative (DR): Matthew Finley

Licensing Company Email: licensure@cardinalhealth.com DR Email: matthew_finley@baxter.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge	N/A			
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

K [signature]
Original Signature (electronic, copies or stamps not accepted)

6/10/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Tessy Plastics Corporation
Address: 700 Visions Dr City: Skaneateles State: NY Zip: 13152
Name: Keytronic Corporation
Address: N. 4424 Sullivan Rd City: Spokane Valley State: WA Zip: 99216
Name: Novanta Corporation
Address: 125 Middlesex Turnpike City: Bedford State: MA Zip: 01730
Name: Flextronics International Asia-Pacific Ltd.
Address: 12455 Research Blvd. City: Austin State: TX Zip: 78759

Section 4: Publicly Traded Corporation

State of Incorporation: New York
Parent Company (if any): see org chart attached - Ultimate parent company is Baxter International, Inc. (Publicly traded)
Corporation Name: Welch Allyn, Inc.
Mailing Address: 4341 State Street Road
City: Skaneateles Falls State: NY Zip: 13153
Telephone: 614-553-3420 Email: licensure@cardinalhealth.com
Contact Person Name: LaToyia Martin

Date of SEC Registration: 3/21/1994 | SEC Registration Number: 0000010456 | Stock Exchange Symbol: BAX

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address: N/A
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Welch Allyn, Inc.

Facility Name

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

K Chamberlain

Original signature of Authorized Person (copies or stamps not accepted)

6/10/2024

Date

Board Use Only	Date Received: 6/14/24	Amount: $1000-ck 10898910

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
WELCH ALLYN, INC.
4341 STATE STREET RD.
Skaneateles Falls, NY 13153
Registration Number: 1318463
FEI Number*: 1316463
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
BAXTER HEALTHCARE CORPORATION[6]
One Baxter Parkway
Deerfield, IL US 60015
Owner/Operator Number: 1417572[7]

Official Correspondent:
Julie Carolan
One Baxter Parkway
Deerfield, IL 60015
Phone: 224-2704340

√verified M.H 6/12/24

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1417572&OwnerOperatorName=&ProductCode=&DeviceName=&Propri
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1417572&OwnerOperatorName=&ProductCode=&DeviceName=&Propri

Page Last Updated: 03/04/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1417572&OwnerOperatorName=&ProductCode=&DeviceName=&Propri
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1417572&OwnerOperatorName=&ProductCode=&DeviceName=&Propri

List of Officers

4341 State Street Road
Skaneateles Falls, New York 13153

Officer Name	Title	Company	Business Address	Business Phone Number
Reazur Rasul	President and Director	Welch Allyn, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-6990
Michael A. Cascella, Jr.	Vice President, Tax	Welch Allyn, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-2000
Karen L. Leets	Vice President and Treasurer	Welch Allyn, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-2000
James William Borzi	SVP, Chief Supply Chain Officer	Welch Allyn, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-2100
Ellen K. Bradford	SVP and Corporate Secretary	Welch Allyn, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-3086

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STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	WELCH ALLYN, INC.
DOS ID Number:	2783610
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	06/27/2002
Statement Status:	CURRENT
Statement Due Date:	06/30/2024

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on March 11, 2024 at 11:42 A.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100005345120 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT A CERTIFICATE EVIDENCING THE CORPORATE EXISTENCE OF "WELCH ALLYN, INC.", A CORPORATION DULY ORGANIZED UNDER THE LAWS OF THE STATE OF NEW YORK, WAS RECEIVED AND FILED IN THIS OFFICE AS A FOREIGN CORPORATION ON FOURTH DAY OF FEBRUARY, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CORPORATION IS QUALIFIED TO DO BUSINESS UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE NOT HAVING BEEN WITHDRAWN OR REVOKED, SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF DELAWARE.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

Jeffrey W. Bullock, Secretary of State

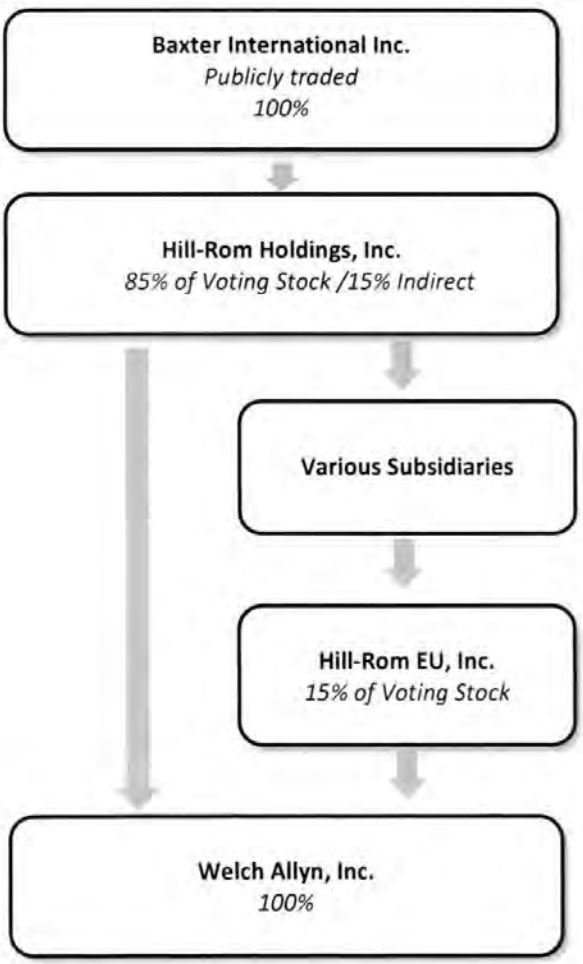
7266524 8360
SR# 20240963673

Authentication: 202997272
Date: 03-12-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

To the best of our knowledge, the answers to the questions included in this application, as they pertain to the facility, officers, directors, owners, and managing employee, are accurate (NO), unless otherwise noted. Although internal recordkeeping regarding discipline is only available since December 13, 2021, due to the recent acquisition of the ultimate parent and subsequent staff turnover, a review of publicly available information indicates that these responses are accurate. However, should information to the contrary be discovered, we will disclose the relevant information to the Program.

Organizational Chart



THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2024-27

NAME OF SUPERVISOR
COLLEEN ALEXANDER

THIS IS TO CERTIFY

WELCH ALLYN, INC.
4341 STATE STREET RD
SKANEATELES FALLS, NY 13153

is duly recorded as a

REGISTERED MANUFACTURER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWENTY-FIFTH DAY OF MARCH, 2024.
THIS CERTIFICATE EXPIRES ON THE TWENTY-EIGHTH DAY OF FEBRUARY, 2027.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
040414

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

0854

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 03/07/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Chicago IL Office 200 East Randolph Chicago IL 60601 USA	PHONE (A/C, No, Ext): (866) 283-7122	FAX (A/C, No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Baxter International Inc and All Affiliates, Divisions, and Subsidiaries thereof including Baxter Healthcare Corp and Hillrom Holdings, Inc. One Baxter Parkway Deerfield IL 60015-4633 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B: Illinois Union Insurance Company	27960
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570104237815 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY5782023	09/01/2023	09/01/2024	EACH OCCURRENCE	$2,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$50,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						MED EXP (Any one person)	$25,000
	[X] POLICY [ ] PRO-JECT [ ] LOC						PERSONAL & ADV INJURY	$2,000,000
	OTHER:						GENERAL AGGREGATE	$4,000,000
							PRODUCTS - COMP/OP AGG	Excluded
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	[ ] ANY AUTO						BODILY INJURY (Per person)	
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
B	X UMBRELLA LIAB X OCCUR			XEUG27981604008	09/01/2023	09/01/2024	EACH OCCURRENCE	$1,000,000
	EXCESS LIAB [ ] CLAIMS-MADE			SIR applies per policy terms & conditions			AGGREGATE	$1,000,000
	DED X RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N / A						E.L. EACH ACCIDENT	
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	
							E.L. DISEASE-POLICY LIMIT	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Locations: 1052 Cassens Industrial Ct., Fenton, MO 63026; 6149 Wedeking Ave., Bldg. D, Suite 3, Evansville, IN 47715; 2443 W. 16th Street, Unit B, Chicago, IL 60608; 1503 N. Kickapoo St., Lincoln, IL 62656, 1020 Veterans Memorial Dr. Ste. A, Mount Vernon, IL 62864 and 9430 Enterprise Dr., Mokena, IL 60448.

CERTIFICATE HOLDER

Hill-Rom Co., Inc.
1069 State Route E.
Batesville IN 47006 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570104237815

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AGENCY CUSTOMER ID: 10224186
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Baxter International Inc and All
POLICY NUMBER: See Certificate Number: 570104237815	
CARRIER: See Certificate Number: 570104237815 / NAIC CODE	EFFECTIVE DATE

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
A	Products Liability			MWZY31692223 SIR applies per policy terms & conditions	09/01/2023	09/01/2024	Each Occurrence	$1,000,000
							Products - Comp/Op Agg	$1,000,000

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Welch Allyn, Inc. MDEG License # (if applicable) _____

Physical Address 4341 State Street Road

City Skaneateles Falls State NY Zip 13153

Mailing Address (if different from physical address) 7000 Cardinal Pl, Attn: QRA

City Dublin State OH Zip 43017

Telephone 315-685-4602 Website www.hillrom.com

Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First Matthew Middle Patrick Last Finley

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 4341 State Street Road

City Skaneateles Falls State NY Zip 13153

Telephone 315-400-9058 Email licensure@cardinalhealth.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
United States Military Academy		07/85 - 05/89	
Address	**City**	**State**	**Zip**
606 Thayer Rd	West Point	NY	10996
Diploma/Degree obtained, if any			
BS History & General Engineering			

School Name		From - To (MM/YY – MM/YY)	
Prattsburg Central School		09/73 - 06/85	
Address	**City**	**State**	**Zip**
1 Academy Street	Prattsburg	NY	14873
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22 - present	[redacted]Old Seneca Tpk	Marcellus	NY	13108
12/21 - 02/22	[redacted]Ridge Rd	Hammondsport	NY	14840
10/15 - 12/21	[redacted]Tulip Way	Medway	MA	02053
05/14 - 10/15	[redacted]	Pewaukee	WI	53072

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Baxter (Formerly known as Hill-rom)			From - To (MM/YY – MM/YY): 10/21 - present	
Business Address: 4341 State Street Road		City: Skaneateles Falls	State: NY	Zip: 13153
Phone: 315-400-9058	Title: Plant Manager		Number of Employed Hours: 5,200	
Description of Duties: Responsible for all manufacturing and supply chain operations (MWER)				

Business Name: Cytiva (Formerly known as GE Life Sciences)			From - To (MM/YY – MM/YY): 03/2017 - 05/2020	
Business Address: 14 Walk-Up Dr		City: Westborough	State: MA	Zip: 01581
Phone: 800-526-3593	Title: Executive Shop Operations		Number of Employed Hours: 7,040	
Description of Duties: Site executive for 2 manufacturing sites responsible for all manufacturing and supply chain operations (MWER)				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic copies or stamps not accepted)

10 June 2024
Date

I, Matthew Finley, **certify that as the MDEG Administrator for**

Welch Allyn, Inc.,

that I (initial that you have read and meet the following requirements):

1. MMF Have a high school diploma or its equivalent;
2. MMF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MMF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MMF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Finley
Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

10 June 2024
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Welch Allyn, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 4341 State Street Road

City Skaneateles Falls State NY Zip 13153

Mailing Address (if different from physical address) 7000 Cardinal Pl. Attn: QRA

City Dublin State OH Zip 43017

Telephone 315-685-4602 Website www.hillrom.com

Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First Matthew Middle Patrick Last Finley

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 4341 State Street Road

City Skaneateles Falls State NY Zip 13153

Telephone 315-400-9058 Email matthew_finley@baxter.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
United States Military Academy		07/85 - 05/89	
Address	**City**	**State**	**Zip**
606 Thayer Road	West Point	NY	10996.
Diploma/Degree obtained, if any			
BS History & General Engineering			

School Name		From - To (MM/YY – MM/YY)	
Prattsburgh Central School		09/73 - 06/85	
Address	**City**	**State**	**Zip**
1 Academy Street	Prattsburgh	NY	14873
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22 - Present	[redacted] Old Seneca Tpk	Marcellus	NY	13108
12/21 to 02/22	[redacted] Ridge Rd.	Hammondsport	NY	14840
10/15 - 12/21	[redacted] Tulip Way	Westwood	MA	02053
5/14 - 10/15	[redacted] Brick St	Pewaukee	WI	53072
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Baxter (Formerly known as Hill-rom)			10/21 - Present
Business Address	**City**	**State**	**Zip**
4341 State Street Road	Skaneateles Falls	NY	13153
Phone	**Title**		**Number of Employed Hours**
315-400-9058	Plant Manager		5,200
Description of Duties	Responsible for all manufacturing and supply chain Operations. (MWER)		

Business Name			From - To (MM/YY – MM/YY)
Cytiva (Formerly known as GE Life Sciences)			03/17 - 08/20
Business Address	**City**	**State**	**Zip**
14 Walk-up Drive	Westborough	MA	01581
Phone	**Title**		**Number of Employed Hours**
800-526-3593	Executive Supp Operations		7,040
Description of Duties	Site Executive For 2 manufacturing sites responsible for all manufacturing and supply chain operations. (MWER)		

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

31 May 2024
Date

I, Matthew Finley, **certify that as the designated representative for**

Welch Allyn, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MA I am at least 21 years of age;
3. MA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Matthew Finley

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3 May 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew P. Finley
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03 June 2024
Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Onondaga

I, Matthew P. Finley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03 June 2024
Date

Subscribed and Sworn to before me this 3rd day of June 2024.

Notary Public Signature

ANTHONY MICHAEL TIRINATO
Notary Public - State of New York
NO. 01TI6338416
Qualified in Onondaga County
My Commission Expires Mar 14, 2028

(Seal)

List of employees:

Matthew Finley - Plant Manager

Reazur Rasul - President and Director

Michael A. Cascella, Jr. - Vice President, Tax

Karen L. Leets - Vice President and Treasurer

James William Borzi - SVP, Chief Supply Chain Officer

Ellen K. Bradford - SVP and Corporate Secretary

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 1-4448

Baxter

Baxter International Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	36-0781
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Emp Identificatic
One Baxter Parkway, Deerfield, Illinois	6001
(Address of Principal Executive Offices)	(Zip Co

Registrant's telephone number, including area code 224.948.2000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Excha
Common stock, $1.00 par value	BAX (NYSE)	New York
		Chicago S
0.4% Global Notes due 2024	BAX 24	New York
1.3% Global Notes due 2025	BAX 25	New York
1.3% Global Notes due 2029	BAX 29	New York

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 dur shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ N

Indicate by check mark whether registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regula preceding 12 months (or for such shorter period that the registrant was required to submit such files) Yes ☑ No ☐

WELCH ALLYN, INC.

DELEGATION OF AUTHORITY

WHEREAS, the Board of Directors of Welch Allyn, Inc., a New York corporation (the "Corporation"), adopted Ordinary Course of Business resolutions on December 13, 2021 (the "Resolutions"), a copy of which is attached; and

WHEREAS, pursuant to the Resolutions, the Corporation's elected officers and employees of the Corporation having the job classifications set forth in Exhibit D of the Resolutions (each an "Authorized Signatory") are authorized and directed to sign any documents relating to matters within the Authorized Signatory's respective job responsibilities, commonly necessary and incidental to the Corporation's business and the execution of which is in the best interest of the Corporation; and

WHEREAS, Baxter International Inc., a direct parent of the Corporation ("Baxter"), changed certain of its officer and management titles, as a result of which all Corporate Vice Presidents are now Senior Vice Presidents or Executive Vice Presidents of Baxter or any subsidiary thereof (including the Corporation) and the "General Managers" contemplated in the exhibit to the Resolutions (the "Resolution Grid") shall now include Presidents or General Managers of one or more of Baxter's Divisions and/or global regions;

WHEREAS, as a result of the changes referenced in the aforementioned clause, all "Corporate Vice President" references in the Resolution Grid are now deemed to relate to and include any Senior Vice President or Executive Vice President of Baxter or any subsidiary thereof (including the Corporation) and all "General Managers" references in the Resolution Grid are now deemed to relate to and include any President or General Manager of one or more of Baxter's Divisions and/or global regions; and

NOW THEREFORE:

As contemplated by the Resolutions, the undersigned Ellen K. Bradford, Vice President and Secretary, an Authorized Signatory, hereby delegates to Keegan Chamberlain, Director of Quality Management and LaToyia Martin, Manager, Quality Compliance, employees of Cardinal Health 200 LLC, the authority to sign for all documents, applications, submissions and other related instruments required for the state pharmacy, wholesale distribution, and manufacturing licenses and legally required permits filed on behalf of the Corporation.

This delegation of authority shall be effective until December 31, 2024 and is subject to revocation by any officer of Welch Allyn, Inc. at any time and shall occur automatically when Keegan Chamberlain or LaToyia Martin ceases to be an employee of Cardinal Health 200 LLC.

The undersigned further approves and ratifies any and all actions taken by Keegan Chamberlain and LaToyia Martin prior to this date, solely in connection with the execution of the above-referenced matters.

Effective: March 18, 2024

Welch Allyn, Inc.

Ellen K. Bradford

Ellen K. Bradford
Vice President and Secretary

EXHIBIT A

Welch Allyn, Inc.
Ordinary Course of Business Resolutions
December 13, 2021

ORDINARY COURSE OF BUSINESS

NOW, THEREFORE, BE IT RESOLVED, that the Corporation's elected officers and employees of the Corporation having the job classifications set forth in Exhibit D (each an "Authorized Signatory") are authorized and directed to sign any documents relating to matters within the Authorized Signatory's respective job responsibilities, commonly necessary and incidental to the Corporation's business and the execution of which is in the best interest of the Corporation;

FURTHER RESOLVED, that each Authorized Signatory shall have the authority to execute such documents that are within the financial limitations as set forth on Exhibit D, which may be updated from time to time without further resolution;

FURTHER RESOLVED, that any Authorized Signat01y is authorized to delegate signing authority ("Delegation") to another individual with such limitations as the Authorized Signatory may establish from time to time, provided however, that any such Delegation shall be in writing in the form of Delegation provided by the office of the Secretary of the Corporation and shall be subject to any limits set forth therein by the Authorized Signatory; FURTHER RESOLVED, that when signing authority is delegated, an original of any such Delegation shall be delivered to the Secretary of the Corporation to be retained as a part of the permanent records of the Corporation; and

FURTHER RESOLVED, that the Secretary or an Assistant Secretary of the Corporation is authorized to attest to the signatures of the Authorized Signatories and affix the seal of the Corporation to such documents, however such documents shall be the binding obligation of the Corporation without the necessity of attestation or affixing of the corporate seal.

EXHIBIT D

ORDINARY COURSE OF BUSINESS SIGNATURE

AUTHORITY TABLE

JOB CLASSIFICATION	FINANCIAL LIMITATION
Chief Executive Officer, Executive Vice President or any Senior Vice President	No limitations
Global Franchise Unit Head	Up to $10 Million
Vice President (including General Manager)	Up to $5 Million
Director	Up to $1 Million

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Quest Pharmaceuticals, Inc.

Physical Address: 300 Chestnut Street

City: Murray State: KY Zip: 42071

Mailing Address (if different from physical address): P O Box 270

City: Murray State: KY Zip: 42071

Telephone: 270-759-1248 Website: www.questpharmaceuticals.com

Name of Designated Representative (DR): Kevin Higgins

Licensing Company Email: _____ DR Email: KHiggins@questpharmaceuticals.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: OTC	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
■ Others: Indigent Care Clinics		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

5/13/24

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Aurobindo Pharma USA, Inc.
Address: 279 Princeton Hightstown Roas City: East Windsor State: NY Zip: 08520
Name: Rising Pharma Holdings, Inc.
Address: 2 Tower Center City: East Brunswick State: NJ Zip: 08816
Name: Sandoz, Inc.
Address: 506 Carnegie Center, Suite 400 City: Princeton State: NJ Zip: 08540
Name: Camber Pharmaceuticals, Inc.
Address: 800 Centenial Avenue City: Piscataway State: NJ Zip: 08854

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Kentucky
Parent Company (if any):
Corporation/Organization Name: Quest Pharmaceuticals, Inc.
Mailing Address: 300 Chestnut Street
City: Murray State: KY Zip: 42071
Telephone: 270-759-1248 Email: JLamb@questpharmaceuticals.com
Contact Person Name: Jenna Lamb

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP_2019_Fingerprinting_Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Quest Pharmaceuticals, Inc.

Facility Name

Kevin Higgins

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/13/24

Date

Board Use Only	Date Received: 5/23/24	Amount: $1000-ck 049375

NABP ACCREDITED

DRUG DISTRIBUTOR

Quest Pharmaceuticals, Inc

located at

300 East Chestnut Street, Murray, KY 42071

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

02/23/2022 - 02/22/2025
Period of Accreditation

0881

Quest Pharmaceuticals, Inc.
300 Chestnut Street
Murray, KY 42071

Corporate Officers

State of Incorporation: Kentucky
FEIN: 61-1245795

Kevin E. Higgins, President 50% Ownership
Home Address:
[redacted] Briensburg Road
Benton, KY 42025
[redacted]

Business Address:
300 Chestnut Street
P.O. Box 270
Murray, KY 42071
(270) 759-1248

Michael Cappock, Vice President 50% Ownership
Home Address:
[redacted] Marlborough Way
Paducah, KY 42001
[redacted]

Business Address:
300 Chestnut Street
P.O. Box 270
Murray, KY 42071
(270) 759-1248

Commonwealth of Kentucky
Michael G. Adams, Secretary of State

Michael G. Adams
Secretary of State
P. O. Box 718
Frankfort, KY 40602-0718
(502) 564-3490
http://www.sos.ky.gov

Certificate of Existence

Authentication number: 309195
Visit https://web.sos.ky.gov/ftshow/certvalidate.aspx to authenticate this certificate.

I, Michael G. Adams, Secretary of State of the Commonwealth of Kentucky, do hereby certify that according to the records in the Office of the Secretary of State,

QUEST PHARMACEUTICALS, INC.

QUEST PHARMACEUTICALS, INC. is a corporation duly incorporated and existing under KRS Chapter 14A and KRS Chapter 271B, whose date of incorporation is August 27, 1993 and whose period of duration is perpetual.

I further certify that all fees and penalties owed to the Secretary of State have been paid; that Articles of Dissolution have not been filed; and that the most recent annual report required by KRS 14A.6-010 has been delivered to the Secretary of State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my Official Seal at Frankfort, Kentucky, this 12th day of April, 2024, in the 232nd year of the Commonwealth.

COMMONWEALTH OF KENTUCKY
OFFICE OF SECRETARY OF STATE

Michael G. Adams
Secretary of State
Commonwealth of Kentucky
309195/0319520

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Wholesale Distributor

EFFECTIVE DATE: 10/06/1993

NUMBER: W00143

EXPIRATION DATE: 09/30/2024

Issued to:
QUEST PHARMACEUTICALS INC

300 E CHESTNUT ST
P0 BOX 270
MURRAY, KY 42071

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address, and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

jlamb@questpharmaceuticals.com

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RQ0188981	04-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-04-2024

QUEST PHARMACEUTICALS INC
300 CHESTNUT ST
PO BOX 270
MURRAY, KY 42071

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D C 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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QUEST PHARMACEUTICALS INC
300 CHESTNUT ST
PO BOX 270
MURRAY, KY 42071

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. E712985

Application/License No. _____

QUEST PHARMACEUTICALS INC, doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
300 CHESTNUT STREET MURRAY, KY 42071, as
(Address of Applicant/Principal)
PRINCIPAL, and Great American Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Ohio
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
300 CHESTNUT STREET MURRAY, KY 42071 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 04/02/2024.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 3rd day of April, 2024

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Michael Neschke, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

GREAT AMERICAN INSURANCE COMPANY®

Administrative Office: 301 E 4TH STREET • CINCINNATI, OHIO 45202 • 513-369-5000 • FAX 513-723-2740

The number of persons authorized by this power of attorney is not more than one

Bond No. E712985

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the GREAT AMERICAN INSURANCE COMPANY, a corporation organized and existing under and by virtue of the laws of the State of Ohio, does hereby nominate, constitute and appoint the person or persons named below its true and lawful attorney-in-fact, for it and in its name, place and stead to execute on behalf of the said Company, as surety, the specific bond, undertaking or contract of suretyship referenced herein; provided that the liability of the said Company on any such bond, undertaking or contract of suretyship executed under this authority shall not exceed the limit stated below. The bond number on this Power of Attorney must match the bond number on the bond to which it is attached or it is invalid.

Name	Address	Limit of Power
Michael Neschke	11205 Lebanon Road #13 Mount Juliet, TN 37122	$25000--

IN WITNESS WHEREOF the GREAT AMERICAN INSURANCE COMPANY has caused these presents to be signed and attested by its appropriate officers and its corporate seal hereunto affixed this 3rd day of April , 2024 .

Attest

GREAT AMERICAN INSURANCE COMPANY

Assistant Secretary

Divisional Senior Vice President

MARK VICARIO (877-377-2405)

STATE OF OHIO, COUNTY OF HAMILTON - ss:

On this 3rd day of April , 2024 , before me personally appeared MARK VICARIO, to me known, being duly sworn, deposes and says that he resides in Cincinnati, Ohio, that he is a Divisional Senior Vice President of the Bond Division of Great American Insurance Company, the Company described in and which executed the above instrument; that he knows the seal of the said Company; that the seal affixed to the said instrument is such corporate seal; that it was so affixed by authority of his office under the By-Laws of said Company, and that he signed his name thereto by like authority.

SUSAN A KOHORST
Notary Public
State of Ohio
My Comm. Expires
May 18, 2025

This Power of Attorney is granted by authority of the following resolutions adopted by the Board of Directors of Great American Insurance Company by unanimous written consent dated June 9, 2008.

RESOLVED: That the Divisional President, the several Divisional Senior Vice Presidents, Divisional Vice Presidents and Divisonal Assistant Vice Presidents, or any one of them, be and hereby is authorized, from time to time, to appoint one or more Attorneys-in-Fact to execute on behalf of the Company, as surety, any and all bonds, undertakings and contracts of suretyship, or other written obligations in the nature thereof; to prescribe their respective duties and the respective limits of their authority; and to revoke any such appointment at any time.

RESOLVED FURTHER: That the Company seal and the signature of any of the aforesaid officers and any Secretary or Assistant Secretary of the Company may be affixed by facsimile to any power of attorney or certificate of either given for the execution of any bond, undertaking, contract of suretyship, or other written obligation in the nature thereof, such signature and seal when so used being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

CERTIFICATION

I, STEPHEN C. BERAHA, Assistant Secretary of Great American Insurance Company, do hereby certify that the foregoing Power of Attorney and the Resolutions of the Board of Directors of June 9, 2008 have not been revoked and are now in full force and effect.

Signed and sealed this 3rd day of April , 2024 .

Assistant Secretary

S1194E (05/20)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Quest Pharmaceuticals, Inc

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 300 Chestnut St.

City Murray State KY Zip 42071

Mailing Address (if different from physical address) PO Box 270

City Murray State KY Zip 42071

Telephone 270-759-1248 Website www.questpharmaceuticals.com

Licensing Company Email JLamb@questpharmaceuticals.com

Section 2: Personal Information

First Kevin Middle Edgar Last Higgins

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 300 Chestnut St.

City Murray State KY Zip 42071

Telephone 270-759-1248 Email KHiggins@questpharmaceuticals.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Samford University		08/80 - 08/82	
Address	**City**	**State**	**Zip**
800 Lakeshore Drive	Birmingham	AL	35229
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Murray State University		08/76 - 08/80	
Address	**City**	**State**	**Zip**
1375 Chestnut Street	Murray	KY	42071
Diploma/Degree obtained, if any			
Bachelor of Science in Biology			
School Name		**From - To (MM/YY – MM/YY)**	
Marshall County High School		08/72 - 05/76	
Address	**City**	**State**	**Zip**
416 High School Road	Benton	KY	42025
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10+ - current	[redacted]Briensburg Rd	Benton	KY	42025
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Quest Pharmaceuticals, Inc			8/31/1993 - Present	
Business Address		**City**	**State**	**Zip**
300 Chestnut St.		Murray	KY	42071
Phone	**Title**		**Number of Employed Hours**	
270-759-1248	President / Owner / RPh		40hr+/ week	
Description of Duties				
Oversees buying and all business operations				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Mar 27, 2013	August 8, 2016	WV		Boone County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Civil Action No. 2:12-3760		Circuit Court of Boone County, WV		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of WV ex rel. Patrick Morrisey v. Amerisourcebergen Drug, et al.				
Name of Business/Industry/Entity				
Quest Pharmaceuticals, Inc.				

Provide explanation below:

Attorney General alleged that the defendants had "failed to diligently respond to suspicious orders which the Defendants have filled" and have "therefore failed to provide effective controls and procedures to guard against" diversion of controlled substances under the Controlled Substances Act.

Lawsuit was dismissed with prejudice. Agreed Order of Dismissal Attached.

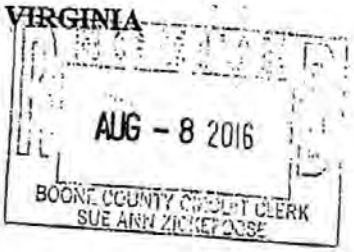
Kevin E Hoffman

Original Signature (electronic, copies or stamps not accepted)

5/13/24

Date

IN THE CIRCUIT COURT OF BOONE COUNTY, WEST VIRGINIA



STATE OF WEST VIRGINIA
ex rel. PATRICK MORRISEY,
Attorney General, *et al.*,

Plaintiffs,

v.

CIVIL ACTION NO. 12-C-141
(Hon. William S. Thompson, Judge)

AMERISOURCEBERGEN DRUG CORP.,
a Delaware corporation doing business in
West Virginia, *et al.*,

Defendants.

AGREED ORDER OF DISMISSAL WITH PREJUDICE

This day came the Plaintiffs, State of West Virginia ex rel Patrick Morrisey, Attorney General, Joseph Thornton, in his capacity as the Secretary of the West Virginia Department of Military Affairs and Public Safety, and Karen Bowling, in her capacity as the Secretary of the West Virginia Department of Health and Human Resources (together "Plaintiffs") by counsel, and defendant, Quest Pharmaceuticals, Inc. (together "the parties"), by their respective counsel, and jointly informed the Court that all matters in controversy in the above-styled action between the parties, whether pleaded or not, have been fully adjusted, compromised, and settled, and therefore, the parties jointly move the Court that the Plaintiffs' claims against defendant Quest Pharmaceuticals, Inc. in this action be DISMISSED WITH PREJUDICE.

Upon consideration thereof and there being no objection, it is hereby ADJUDGED and ORDERED that this case be, and hereby is, DISMISSED WITH PREJUDICE between the Plaintiffs and defendant Quest Pharmaceuticals, Inc., as all matters in controversy between the

parties have been fully adjusted, compromised and settled. It is further ORDERED that this matter remain on the active docket of this Court as to all remaining parties.

The Clerk is hereby directed to forward certified copies of this Order to all counsel of record.

ENTERED this 8th day of August, 2016.

HONORABLE WILLIAM S. THOMPSON
Circuit Court Judge

Agreed to by:

Sean P. McGinley (WVSB #5836)
DiTrapano Barrett DiPiero
McGinley & Simmons, PLLC
604 Virginia St. East
Charleston, WV 25301
Counsel for Plaintiffs

David E. Schumacher, Esq.
Bailey & Wyant
500 Virginia Street East, Suite 600
PO Box 3710
Charleston, West Virginia 25337
Counsel for Quest Pharmaceuticals, Inc.

A COPY ATTEST

Lee Ann Zickafoose

CIRCUIT COURT

I, Kevin Edgar Higgins, **certify that as the designated representative for**

Quest Pharmaceuticals, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kevin Higgins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/13/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Higgins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/13/24

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Calloway

I, Kevin Higgins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/13/24

Date

Subscribed and Sworn to before me this 13th day of May.

Shelenia Carol Underhill Mest

Notary Public Signature

SHELENIA CAROL UNDERHILL
Notary Public
Commonwealth of Kentucky
Commission Number KYNP40301
My Commission Expires Jan 4, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Quest Pharmaceuticals, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 300 Chestnut St.

City: Murray State: KY Zip: 42071

Mailing Address (if different from physical address): PO Box 270

City: Murray State: KY Zip: 42071

Telephone: 270-759-1248 Website: www.questpharmaceuticals.com

Licensing Company Email: JLamb@questpharmaceuticals.com

Section 2: Personal Information

First: Kevin Middle: Edgar Last: Higgins

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]riensburg Rd

City: Benton State: KY Zip: 42025

Telephone: 270-759-1248 Email: KHiggins@questpharmaceuticals.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Samford University		08/80 - 08/82	
Address	**City**	**State**	**Zip**
800 Lakeshore Drive	Birmingham	AL	35229
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Murray State University		08/76 - 08/80	
Address	**City**	**State**	**Zip**
1375 Chestnut Street	Murray	KY	42071
Diploma/Degree obtained, if any			
Bachelor of Science in Biology			
School Name		**From - To (MM/YY – MM/YY)**	
Marshall County High School		08/72 - 05/76	
Address	**City**	**State**	**Zip**
416 High School Road	Benton	KY	42025
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10+ - current	[redacted]Briensburg Rd	Benton	KY	42025
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Quest Pharmaceuticals, Inc			8/31/1993 - Present	
Business Address		**City**	**State**	**Zip**
300 Chestnut St.		Murray	KY	42071
Phone	**Title**			
270-759-1248	President / Owner / RPh			
Description of Duties				
Oversees buying and all business operations				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Mar 27, 2013	August 8, 2016	WV		Boone County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
Civil Action No. 2:12-3760	Circuit Court of Boone County, WV

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
State of WV ex rel. Patrick Morrisey v. Amerisourcebergen Drug, et al.	

Name of Business/Industry/Entity
Quest Pharmaceuticals, Inc.

Provide explanation below:

Attorney General alleged that the defendants had "failed to diligently respond to suspicious orders which the Defendants have filled" and have "therefore failed to provide effective controls and procedures to guard against" diversion of controlled substances under the Controlled Substances Act.

Lawsuit was dismissed with prejudice. Agreed Order of Dismissal Attached.

Kevin Higgs

Original Signature (electronic, copies or stamps not accepted)

5/13/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Higgins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/13/24

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Calloway

I, Kevin Higgins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/13/24

Date

Subscribed and Sworn to before me this 13th day of May.

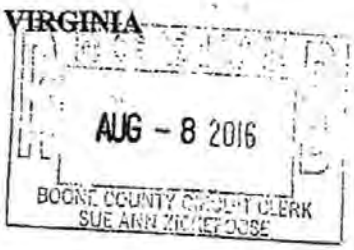
Shelenia Carol Underhill West

Notary Public Signature

SHELENIA CAROL UNDERHILL
Notary Public
Commonwealth of Kentucky
Commission Number KYNP40301
My Commission Expires Jan 4, 2026

(Seal)

IN THE CIRCUIT COURT OF BOONE COUNTY, WEST VIRGINIA



STATE OF WEST VIRGINIA
ex rel. PATRICK MORRISEY,
Attorney General, *et al.*,

Plaintiffs,

v.

CIVIL ACTION NO. 12-C-141
(Hon. William S. Thompson, Judge)

AMERISOURCEBERGEN DRUG CORP.,
a Delaware corporation doing business in
West Virginia, *et al.*,

Defendants.

AGREED ORDER OF DISMISSAL WITH PREJUDICE

This day came the Plaintiffs, State of West Virginia ex rel Patrick Morrisey, Attorney General, Joseph Thornton, in his capacity as the Secretary of the West Virginia Department of Military Affairs and Public Safety, and Karen Bowling, in her capacity as the Secretary of the West Virginia Department of Health and Human Resources (together "Plaintiffs") by counsel, and defendant, Quest Pharmaceuticals, Inc. (together "the parties"), by their respective counsel, and jointly informed the Court that all matters in controversy in the above-styled action between the parties, whether pleaded or not, have been fully adjusted, compromised, and settled, and therefore, the parties jointly move the Court that the Plaintiffs' claims against defendant Quest Pharmaceuticals, Inc. in this action be DISMISSED WITH PREJUDICE.

Upon consideration thereof and there being no objection, it is hereby ADJUDGED and ORDERED that this case be, and hereby is, DISMISSED WITH PREJUDICE between the Plaintiffs and defendant Quest Pharmaceuticals, Inc., as all matters in controversy between the

parties have been fully adjusted, compromised and settled. It is further ORDERED that this matter remain on the active docket of this Court as to all remaining parties.

The Clerk is hereby directed to forward certified copies of this Order to all counsel of record.

ENTERED this 8th day of August, 2016.

HONORABLE WILLIAM S. THOMPSON
Circuit Court Judge

Agreed to by:

Sean R. McGinley (WVSB #5836)
DiTrapano Barrett DiPiero
McGinley & Simmons, PLLC
604 Virginia St. East
Charleston, WV 25301
Counsel for Plaintiffs

David E. Schumacher, Esq.
Bailey & Wyant
500 Virginia Street East, Suite 600
PO Box 3710
Charleston, West Virginia 25337
Counsel for Quest Pharmaceuticals, Inc.

A COPY ATTEST

Lee Ann Zickefoose

CIRCUIT COURT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Quest Pharmaceuticals, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 300 Chestnut St.

City Murray State KY Zip 42071

Mailing Address (if different from physical address) PO Box 270

City Murray State KY Zip 42071

Telephone 270-759-1248 Website www.questpharmaceuticals.com

Licensing Company Email JLamb@questpharmaceuticals.com

Section 2: Personal Information

First Michael Middle Christopher Last Cappock

Alias(es, nicknames, name changes, etc.) Mike

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Marlborough Way

City Paducah State KY Zip 42002

Telephone 270-759-1248 Email MCappock@questpharmaceuticals.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Murray State University		08/80 - 05/87	
Address	**City**	**State**	**Zip**
1800 Sycamore Street	Murray	KY	42071
Diploma/Degree obtained, if any			
BS Degree			

School Name		From - To (MM/YY – MM/YY)	
Murray High School		08/77 - 05/80	
Address	**City**	**State**	**Zip**
1375 Chestnut Street	Murray	KY	42071
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10+ - current	[redacted]Marlborough Way	Paducah	KY	42002
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Quest Pharmaceuticals, Inc.			08/93 - Current
Business Address	**City**	**State**	**Zip**
300 Chestnut Street	Murray	KY	42071
Phone	**Title**		
270-759-1248	Vice President / Owner		
Description of Duties			
In charge of overseeing the sales team and warehouse manager/operations.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Mar 27, 2013	August 8, 2016	WV		Boone County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Civil Action No. 2:12-3760		Circuit Court of Boone County, WV		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of WV ex rel. Patrick Morrisey v. Amerisourcebergen Drug, et al.				
Name of Business/Industry/Entity				
Quest Pharmaceuticals, Inc.				

Provide explanation below:

Attorney General alleged that the defendants had "failed to diligently respond to suspicious orders which the Defendants have filled" and have "therefore failed to provide effective controls and procedures to guard against" diversion of controlled substances under the Controlled Substances Act.

Lawsuit was dismissed with prejudice. Agreed Order of Dismissal Attached.

Original Signature (electronic, copies or stamps not accepted)

5-14-24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Cappock

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-14-24

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Calloway

I, Mike Cappock, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5-14-24

Date

Subscribed and Sworn to before me this 14th day of May.

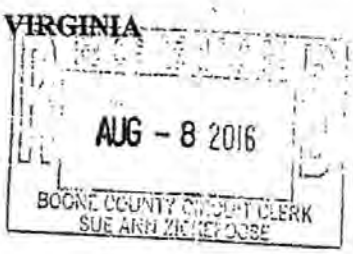
Shelenia Carol Underhill West

Notary Public Signature

SHELENIA CAROL UNDERHILL
Notary Public
Commonwealth of Kentucky
Commission Number KYNP40301
My Commission Expires Jan 4, 2026

(Seal)

IN THE CIRCUIT COURT OF BOONE COUNTY, WEST VIRGINIA



STATE OF WEST VIRGINIA
ex rel. PATRICK MORRISEY,
Attorney General, *et al.*,

Plaintiffs,

v.

CIVIL ACTION NO. 12-C-141
(Hon. William S. Thompson, Judge)

AMERISOURCEBERGEN DRUG CORP.,
a Delaware corporation doing business in
West Virginia, *et al.*,

Defendants.

AGREED ORDER OF DISMISSAL WITH PREJUDICE

This day came the Plaintiffs, State of West Virginia ex rel Patrick Morrisey, Attorney General, Joseph Thornton, in his capacity as the Secretary of the West Virginia Department of Military Affairs and Public Safety, and Karen Bowling, in her capacity as the Secretary of the West Virginia Department of Health and Human Resources (together "Plaintiffs") by counsel, and defendant, Quest Pharmaceuticals, Inc. (together "the parties"), by their respective counsel, and jointly informed the Court that all matters in controversy in the above-styled action between the parties, whether pleaded or not, have been fully adjusted, compromised, and settled, and therefore, the parties jointly move the Court that the Plaintiffs' claims against defendant Quest Pharmaceuticals, Inc. in this action be DISMISSED WITH PREJUDICE.

Upon consideration thereof and there being no objection, it is hereby ADJUDGED and ORDERED that this case be, and hereby is, DISMISSED WITH PREJUDICE between the Plaintiffs and defendant Quest Pharmaceuticals, Inc., as all matters in controversy between the

parties have been fully adjusted, compromised and settled. It is further ORDERED that this matter remain on the active docket of this Court as to all remaining parties.

The Clerk is hereby directed to forward certified copies of this Order to all counsel of record.

ENTERED this 8th day of August, 2016.

Wilson

HONORABLE WILLIAM S. THOMPSON
Circuit Court Judge

Agreed to by:

Sean P. McGinley (WVSB #5836)
DiTrapano Barrett DiPiero
McGinley & Simmons, PLLC
604 Virginia St. East
Charleston, WV 25301
Counsel for Plaintiffs

David E. Schumacher, Esq.
Bailey & Wyant
500 Virginia Street East, Suite 600
PO Box 3710
Charleston, West Virginia 25337
Counsel for Quest Pharmaceuticals, Inc.

A COPY ATTEST

Lee Ann Zickefoose

CIRCUIT COURT

Employee Name
Adamson, Hayden
Ahart, Tyler
Archer, Deanne M
Bailey, Amber
Bazzell, Kolt
Bazzell, Zach
Bell, Lydia
Brotherson, Max
Brown, Zach
Casey, Alex
Cappock, Mike
Chiles, Madison
Clark, Alex
Cooper, Aimee
Coriell, Peyton
Cornelison, Chase
Curling, Collin
Custer, Isaac
Darnell, Jarrett
Ethridge, Alyssa
Evans, Virgie G
Fahrenholz, Wendy
Fogle, Nancy S
Gabriel, Heather L
Galloway, Jama
Garner, Blake
Garner, Jayna
Garrison, Evan
Gillum, Caleb
Goode, Lauren
Greer, Timothy R
Haley, Karson
Higgins, Kevin
Hill, Lauren
Houston, Stacey M
Howle, Stacey
Hudson, Benjamin L
Kirks, Amy
Lamb, Jenna R
Lilly, Austin R
Loaiza, Axel
Luker, Samantha

Employee Name
Lupfer, Camden
Malone, Darlene C
McGee, Malle
Mcleod, Nekesha L
Miller, Austin
Moyers, Julie
Murphy, Lora A
Orr, Michael S
Owen, Teresa
Page Jr, Eddie L
Patterson, Candy
Pittman, Janet
Pruitt, Carolina
Ramias, Laura
Schmidt, Mason
Schroeder, Kelsey
Sheppard, Michele
Shields, Brady
Springer, John
Stevens, Reid
Stubbs, Andrew
Thorn, Konner
Tranbarger, Robert B
Trice, Gwendolyn B
Vance, Molly
Warren, Chaney
Weatherford, Austin
West, Shelenia C
Wheeler, Venita R
Wilburn, Carlie
Williams, Sandy
Wilson, Reese

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: RxCrossroads 3PL LLC

Physical Address: 170 Clermont Rd STE A

City: Shepherdsville State: KY Zip: 40165

Mailing Address (if different from physical address): Same as Physical

City: _____ State: _____ Zip: _____

Telephone: 502-357-1310 Website: www.rxcrossroads.com

Name of Designated Representative (DR): Gary Browning

Licensing Company Email: mckessonlicensing@mckesson.co DR Email: Gary.Browning@mckesson.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Wholesale Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Baxalta US Inc
Address: 1200 Lakeside Drive City: Bannockburn State: IL Zip: 60015
Name: Baxter Healthcare Corporation
Address: 1 Baxter Parkway City: Deerfield State: IL Zip: 60015
Name: ModernaTX, Inc
Address: 200 Technology Square City: Cambridge State: MA Zip: 02139
Name: Astellas Pharma US Inc
Address: One Astellas Way City: Northbrook State: IL Zip: 60062

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): RxC Acquisition Company
Corporation/Organization Name: RxCrossroads 3PL LLC
Mailing Address: 6535 State HWY 161
City: Irving State: TX Zip: 75039
Telephone: 972-446-4800 Email: mckessonlicensing@mckesson.com
Contact Person Name: Christopher Carter

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

RxCrossroads 3PL LLC

Facility Name

Christopher Carter

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

09Apr2024

Date

Board Use Only	Date Received: 5/8/24	Amount: $1000-CC

RxCrossroads
By McKesson

RxCrossroads 3PL LLC

Delaware Limited Liability Company incorporated on January 4th 2019.

Parent Company: RxC Acquisition Company
6535 State Highway 161
Irving, TX 75039
FEIN: 20-3113620

Corporate Officers:

Kevin Kettler, President
6535 State HWY 161 Irving, TX 75039

Saralisa Brau, Secretary
6535 State HWY 161 Irving, TX 75039

Holly Weiss, Vice President & Treasurer
6535 State HWY 161 Irving, TX 75039

Christopher Cater, Vice President
6535 State HWY 161 Irving, TX 75039

Anthony Record, Vice President
6535 State HWY 161 Irving, TX 75039

Confidentiality Notice: This document, including any attachments, is for the sole use of its intended recipients and may contain confidential, proprietary and/or privileged information of McKesson Corporation or its affiliates. Any unauthorized review, use, disclosure or distribution is prohibited.

RxCrossroads
By McKesson

Fingerprints not submitted as the ultimate parent company is publicly traded (McKesson Corporation). Additionally, NABP is in the final steps for approval.

If you have any further questions please reach out to Courtney.Phelps@mckesson.com

Confidentiality Notice: This document, including any attachments, is for the sole use of its intended recipients and may contain confidential, proprietary and/or privileged information of McKesson Corporation or its affiliates. Any unauthorized review, use, disclosure or distribution is prohibited.

NABP ACCREDITED

DRUG DISTRIBUTOR

RxCrossroads 3PL LLC

located at

170 Clermont Road, Ste A, Shepherdsville, KY 40165

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

05/29/2023 - 05/28/2026

Period of Accreditation

0923

RxCrossroads
By McKesson

RxCrossroads 3PL LLC

List of Ownership



Confidentiality Notice: This document, including any attachments, is for the sole use of its intended recipients and may contain confidential, proprietary and/or privileged information of McKesson Corporation or its affiliates. Any unauthorized review, use, disclosure or distribution is prohibited.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RXCROSSROADS 3PL LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTEENTH DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RXCROSSROADS 3PL LLC" WAS FORMED ON THE FOURTH DAY OF JANUARY, A.D. 2019.





7223511 8300

SR# 20242152930

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203486397

Date: 05-15-24

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Third Party Logistic

NUMBER: TPL00416

EFFECTIVE DATE: 05/18/2022

EXPIRATION DATE: 06/30/2025

Issued to:
RXCROSSROADS 3PL LLC

170 CLERMONT ROAD
STE A
SHEPHERDSVILLE, KY 40165

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address. and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

mckessonlicensing@mckesson.com

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	04-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-02-2024

RXCROSSROADS 3PL LLC
170 CLERMONT RD STE A
SHEPHERDSVILLE, KY 401658826

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	04-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-02-2024

RXCROSSROADS 3PL LLC
170 CLERMONT RD STE A
SHEPHERDSVILLE, KY 401658826

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	04-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-02-2024

RXCROSSROADS 3PL LLC
170 CLERMONT RD STE A
SHEPHERDSVILLE, KY 401658826

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2012

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. [redacted]

Application/License No. _____

RxCrossroads 3PL, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 170 Clermont Road STE A., Shepherdsville, KY 40165 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 1, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1 day of July, 2022.

APPLICANT/PRINCIPAL
RxCrossroads 3PL, LLC

Authorized Representative

SURETY COMPANY
Liberty Mutual Insurance Company

Surety Company's Representative

Barbara Norton, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent
Barbara Norton, Non-Resident NV License #664119

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No. 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Barbara Norton

all of the city of Houston, state of Texas each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

TERESA PASTELLA COMMONWEALTH OF PENNSYLVANIA NOTARY PUBLIC

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1125044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 1st day of July, 2022.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Marsh MSurety POA LMIC OCIC WAIC Multi Co_022021

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RxCrossroads 3PL LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 170 Clermont Rd STE A

City Shepherdsville State KY Zip 40165

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 502-357-1310 Website www.RxCrossroads.com

Licensing Company Email mckessonlicensing@mckesson.com

Section 2: Personal Information

First Gary Middle L Last Browning

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 170 Clermont Rd. STE A

City Shepherdsville State KY Zip 40165

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Ashford University				
Address		City	State	Zip
180 S. Arizona Ave		Chandler	AZ	85225
Diploma/Degree obtained, if any				
General Studies				

School Name			From - To (MM/YY – MM/YY)	
South Charleston High School			08/96 - 06/98	
Address		City	State	Zip
1 Eagle Way		South Charleston	WV	25309
Diploma/Degree obtained, if any				
Diploma				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2014 - Current	[redacted] Donerail Way	Louisville	KY	40272
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
RxCrossroads 3PL LLC			2014-Current	
Business Address		**City**	**State**	**Zip**
170 Clermont Rd STE A		Shepherdsville	KY	40165
Phone	**Title**		**Number of Employed Hours**	
502-357-1310	Inventory Manager		~20,800	
Description of Duties				
Responsible for inventory management including, but not limited to, receiving, warehouse, wholesale distribution and record keeping of prescription devices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Gary Browning, **certify that as the designated representative for**

RxCrossroads 3PLLLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. GB I am at least 21 years of age;
3. GB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. GB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. GB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. GB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. GB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Gary Browning

Print Name (First, Last)

Original Signature (electronic, ~~copies~~ or stamps not accepted)

04-23-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gary Browning

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04-23-24

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Bullitt

I, Gary Browning, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04-23-24

Date

Subscribed and Sworn to before me this 23rd day of April.

Notary Public Signature

expires 080125

IB # KY NOP33201

(Seal)

Name
Abbott, Michele
Allen, Dawson
Andis Ramírez Aguilar, Kley
Baker, Cortez
BALLARD, Rae
Bolin, Teddy
Bookmiller, Betty
Browning, Gary L
Cain, Christopher
Chandler, Fred
Davis, Marcus Deshaun
Deats, Angela
Fernandez, Bryan
Flores, Carlos Alfredo
Fowler, David
Garrett, Benjamin David
Garriga Perez, Miguel
Garriga, Michel Alejandro
Gassman, Laura Catherine
Gonzalez, Isis Ainelys
Haley, Carolyn
Hardison, Hunter
Hazelwood, Franklin
Isham, Ciara
Johnson, Jeremiah
Jordan, Pat
Kraemer, Samantha
Lama, Nima
Lamont, Nova
Mattingly, Timothy Brian
McElroy-Hitsman, Elizabeth
Mclemore, John
Meade, Matthew
Miller, Crystal
Mitchell, Kerri
Neal, Timothy
Neh, Neh
Njuguna, Kory
Nunez Delgado, Oscar
Obannon, Drew
Ott, Joseph
Paddy, Donald L
Patterson, Sheila
Paw, Mu Yu
Peña Baez, Reynier E
Pena Raset, Carlos J
Ricketts, Latonya
Rodriguez, Kristie
Samb, Mambaye
Sanders, Ernest
Santos, Doralkys
Sellinger, Joe
Simmons, Richard

Stowe, James
Straub, Christine
Sutherland, Melissa
Swain, Tyler
Vaughn, Dayce
Vazquez, Britton
Warden, Toni
Zimmerman, Chris

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
04/2023	04/2023	PA		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	PA Board of Pharmacy

Reason/Charge
Please see attached/below

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Please see attached/below	Please see attached/below

Name of Business/Industry/Entity
RxC Acquisition Company d/b/a RxCrossroads by McKesson

Provide explanation below:

In April 2023, RxC Acquisition Company dba RxCrossroads by McKesson received a disciplinary Order from the Pennsylvania Board of Pharmacy regarding its pharmacy located at 5101 Jeff Commerce Drive, Suite A, Louisville, KY 40219. The Order holds that the pharmacy failed to timely notify the Pennsylvania Board of a change in Pharmacist-in-Charge. However, the pharmacy was able to demonstrate that it completed at least partial notice within the necessary timeframe and thus was only issued a nominal fine of $250. RxCrossroads by McKesson immediately submitted payment of the $250 fine on April 12, 2023.

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/25/2022	05/25/2022	HI		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	HI Board of Pharmacy

Reason/Charge
Please see attached/below

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Please see attached/below	Please see attached/below

Name of Business/Industry/Entity
RxC Acquisition Company d/b/a RxCrossroads by McKesson

Provide explanation below:

On May 25, 2022, RxC Acquisition Company d/b/a RxCrossroads by McKesson entered into a Settlement Agreement with the Hawaii Board of Pharmacy based the pharmacy's December 2021 Kentucky Agreed Order against its pharmacy in Louisville, KY. The Hawaii Settlement Agreement constituted reciprocal discipline and was not based on any newfound violations. A monetary penalty of $500 was imposed.

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/07/2021	12/07/2021	KY		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	KY Board of Pharmacy

Reason/Charge
Please see attached/below

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Please see attached/below	Please see attached/below

Name of Business/Industry/Entity
RxC Acquisition Company d/b/a RxCrossroads by McKesson

Provide explanation below:

On December 7, 2021, RxC Acquisition Company d/b/a RxCrossroads by McKesson received Agreed Order from the Kentucky Board of Pharmacy regarding its pharmacy located in Louisville, KY. The two matters pertain to two patient complaints regarding long hold times experienced on calls to the pharmacy, a malfunction with an automatic refilling program for a patient, and delays in delivering prescriptions, all due to extenuating circumstances. A monetary penalty of $5,000 was imposed.

Original Signature (electronic, copies or stamps not accepted)

09Apr 2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/17/2018	12/17/2018	VA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		VA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On December 17, 2018, in response to the DEA Settlement, McKesson Corporation entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01/14/2019	01/14/2019	CT	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CT Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On January 14, 2019, McKesson Corporation entered into a settlement for a payment of $10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

Original Signature (electronic, copies or stamps not accepted)

09-Apr-2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/27/2019	02/27/2019	WI	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		WI Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On February 27, 2019, in response to the DEA Settlement, McKesson Corporation entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/10/2019	05/10/2019	NM	N/A	N/A

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	NM Board of Pharmacy

Reason/Charge
Please see attached/below

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Please see attached/below	Please see attached/below

Name of Business/Industry/Entity
McKesson Corporation

Provide explanation below:

On May 10, 2019, in response to the DEA Settlement, McKesson Corporation entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by New Mexico aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/21/2019	05/21/2019	AL	N/A	N/A

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	AL Board of Pharmacy

Reason/Charge
Please see attached/below

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Please see attached/below	Please see attached/below

Name of Business/Industry/Entity
McKesson Corporation

Provide explanation below:

On May 21, 2019, in response to the DEA Settlement, McKesson Corporation entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio and Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars ($15,000).

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024
Date

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This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/10/2019	06/10/2019	VA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		VA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On June 10, 2019, in response to the DEA Settlement, McKesson Corporation entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024
Date

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This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/29/2019	06/29/2019	CA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On June 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reproval with McKesson Corporation (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to both the Washington Court House, Ohio and Livonia, MI distribution centers. Subject to the terms of the settlement, McKesson was issued a public letter of Reproval, agreed to pay $4,000 in investigative fees.



Original Signature (electronic, copies or stamps not accepted)

09-Apr-2024

Date

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This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/29/2019	08/29/2019	CO	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CO Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On August 29, 2019, McKesson Corporation received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("McKesson St. Louis").

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024
Date

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This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/29/2019	08/29/2019	CO	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CO Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On August 29, 2019, McKesson Corporation entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("McKesson Chicagoland"). The terms of the settlement included a fine in the amount of $1,150.00.

Original Signature (electronic, copies or stamps not accepted)

09Apr2024
Date

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This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01/07/2020	01/07/2020	IA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		IA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On January 7, 2020, McKesson Corporation entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products that had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and butalbital products that continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019 (the "2020 Clear Lake Consent").

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024

Date

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This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/20/2020	02/20/2020	IN	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		IN Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On February 20, 2020, in response to the DEA Settlement, McKesson Corporation entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

Original Signature (electronic, copies or stamps not accepted)

09Apr2024

Date

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This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/22/2021	05/22/2021	IL	N/A	N/A

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	IL Board of Pharmacy

Reason/Charge
Please see attached/below

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Please see attached/below	Please see attached/below

Name of Business/Industry/Entity
McKesson Corporation

Provide explanation below:

On May 22, 2021, in response to the DEA Settlement, McKesson Corporation entered into a final agreement with the Illinois Department of Financial and Professional Regulation. The Illinois Consent Order applies to the McKesson distribution centers located in Aurora, Colorado, Livonia, Michigan and Washington Court House, Ohio.

- Aurora, Colorado - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2020 except for various exceptions that mirror exceptions in the DEA settlement;
- Livonia, Michigan - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

Original Signature (electronic, copies or stamps not accepted)

09Apr2024
Date

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This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/27/2021	05/27/2021	ME	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		ME Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On May 27, 2021, McKesson Corporation entered into a consent agreement with the Maine Board of Pharmacy regarding its Aurora, IL distribution center failing to report the Colorado disciplinary action to the Maine Board of Pharmacy within 10 days as required. The Colorado disciplinary action is now reported to the Maine Board of Pharmacy. The terms of the consent agreement included a fine in the amount of $500.00.

Original Signature (electronic, copies or stamps not accepted)

09Apr2024
Date

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This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/20/2021	12/20/2021	IL	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		IL Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On December 20, 2021, McKesson Corporation entered into a Consent Order with the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (the "IDFPR") based on reciprocal state action from the 2020 Clear Lake Consent. The Illinois Consent applied to McKesson's Clear Lake, IA distribution center. Under the terms of the Illinois Consent Order, the facility was subject to a public reprimand by the IDFPR.

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/24/2022	03/24/2022	CA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On March 24, 2022, McKesson Corporation and the California Board of Pharmacy (the "Board") entered into a settlement agreement which resolved allegations against McKesson relating to the sale of controlled substances in 2017 and 2018 to an outpatient hospital pharmacy that the pharmacy discovered were being stolen by a pharmacy employee. Pursuant to the settlement agreement, the Board publicly reproved McKesson's Santa Fe Springs distribution center permit, and McKesson agreed to pay the board's costs related to the investigation and enforcement of the matter. As set forth in the settlement agreement, McKesson denies any allegation that it violated California laws regarding the distribution of controlled substances and there are no findings of any violation of state or federal laws.



Original Signature (electronic, copies or stamps not accepted)

09Apr-2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
07/22/2023	07/22/2023	AL	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		AL Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On July 22, 2023, McKesson Corporation's Santa Fe Springs, CA distribution center entered into a Consent Order with the Alabama Board of Pharmacy. The Consent Order constitutes reciprocal disciplinary action that was based entirely on a February 22, 2022, Decision and Order from the California Board of Pharmacy. There were no new facts giving rise to the Alabama Consent. Your office was notified of the California Order on or about 03/25/2022. Pursuant to the terms of the Alabama Consent, McKesson agreed to pay a fine of $25,000.

Original Signature (electronic, copies or stamps not accepted)

09 Apr 2024
Date

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425.

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RM0173055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration RM0220537, located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at 7009 South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at 10504 McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration PM0021535, located at 3775 Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f. The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1 Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number PM0018425.

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number PM0030849. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration RM0220688, will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration RM0220688, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration PM0000771, for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, *e.g.*, administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration PM0018425, and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration RM0220688, and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or

e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, 145 N St. NE (2 Constitution Square), 2nd Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
6535 State Highway 161
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

7. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8. Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9 Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

By Louis J. Milione for

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

March 17, 2017

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

MCKESSON CORPORATION
MCKESSON DRUG COMPANY
[redacted] Plymouth Road
Livonia, MI 48150

Sir/Madam:

This letter is to make notification that Class 2A Distributor (Out-of-State) license #02A0451 (exp. 4/22/2017) shall be renewed; however, said license is **SUSPENDED**, effective immediately.

This New York State controlled substance distribution suspension is based on **MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY** (38220 Plymouth Road, Livonia, MI 48150) failure to comply with 10 NYCRR 80.11(g)(2) which requires that:

> (2) the out-of-state distributor possesses a valid U.S. Drug Enforcement Administration registration

The Bureau of Narcotic Enforcement recognizes the DEA Distributor registration suspension period imposed by the D.E.A. is expected to last until 1/17/2019.

The Bureau of Narcotic Enforcement further recognizes, however, that pursuant to an agreement with the D.E.A., **MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY** (38220 Plymouth Road, Livonia, MI 48150) has been permitted to continue to ship controlled substances from to customers that purchase products under its pharmaceutical prime vendor contract with the Department of Veterans Affairs. Therefore, such limited controlled substance distribution activity shall be permitted by the Bureau within New York State, so long as the agreement with the D.E.A. is in effect.

MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY (38220 Plymouth Road, Livonia, MI 48150) can reapply to the Bureau for full controlled substance distribution authority within New York after the D.E.A. registration suspension has been lifted.

Please feel free to contact me at [redacted] with any questions.

Sincerely,

Michele Mulloy
Regulatory Compliance Section Manager
NYS DOH Bureau of Narcotic Enforcement

Enclosure

Idaho State Board of Pharmacy

1199 Shoreline Ln., Suite 303 P.O. Box 83720 Boise, Idaho 83720-0067
Telephone (208) 334-2356 FAX (208) 334-3536 http://bop.idaho.gov

June 29, 2017

Certified Mail, Return Receipt Requested
and Regular Mail

Nicholas Davis
McKesson Corporation
[redacted] Plymouth Road
Livonia, MI 48150

Re: McKesson Corporation
[redacted]

Dear Mr. Davis,

A copy of the Amended Order Restricting Controlled Substance Registration regarding your client, McKesson Corporation that was executed June 29, 2017 is enclosed. The Order became effective as of the date of execution. As this is a legal document, we recommend you provide a copy to your client for their records.

If you have any questions regarding this matter, please feel free to contact me.

Sincerely,

Alex J. Adams, PharmD, MPH
Executive Director

c. Berk Fraser, Deputy Executive Director

Enc Order BOP 17-055

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the License and Registration of: MCKESSON CORPORATION, Wholesale Distributor License No. W2545, CS Distributor Registration No. D581, Respondent.	[redacted] **AMENDED ORDER RESTRICTING CONTROLLED SUBSTANCE REGISTRATION**

WHEREAS, information has been received by the Idaho Board of Pharmacy ("Board") that constitutes sufficient grounds for the initiation of an administrative action against the controlled substance registration of McKesson Corporation ("Respondent"), a wholesale distributor of controlled substances that is a division of McKesson Corporation ("McKesson");

WHEREAS, Respondent is located in Livonia, Michigan, and is a licensee and registrant of the Board, holding Wholesale Distributor License No. W2545 and Controlled Substance Distributor Registration No. D581 to distribute drug products into the state of Idaho ("Respondent");

WHEREAS, Respondent's license and registration are subject to the provisions of title 54, chapter 17, Idaho Code, title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 27.01.01, *et seq.*;

WHEREAS, the Board is authorized, pursuant to Idaho Code § 54-1728(5) and § 37-2718(a)(3), to enter an order without further hearing or proceeding, which suspends, restricts, limits or otherwise affects Respondent's license and/or controlled substance registration in the same fashion as the action taken against Respondent's federal controlled substance registration by the Drug Enforcement Administration;

WHEREAS, based upon the information presented to the Board by Respondent's legal counsel on January 18, 2017, the Board is advised as follows:

1. McKesson has entered into a settlement agreement with the United States, acting through the U.S. Department of Justice ("DOJ") dated effective January 17, 2017, which attached terms and conditions set forth in the Administrative Memorandum of Agreement dated effective January 17, 2017 (collectively, the "Settlement Agreement"). The Settlement Agreement resulted from the DOJ's contention that it had certain civil claims against McKesson for not meeting its obligations under a prior agreement. The DOJ also contended it had civil claims against McKesson for failure to properly monitor its sales of controlled substances; failure to conduct adequate due diligence and keep accurate records of its sales; failure to maintain effective controls against diversion of particular controlled substances into channels other than legitimate medical, scientific and industrial channels; and failure to report suspicious orders of controlled substances to the U.S. Drug Enforcement Administration ("DEA").

2. McKesson conducts its sales and distribution of controlled substances via its Distribution Centers located across the United States. Twelve Distribution Centers were referenced in the Settlement Agreement. Under the terms of the Settlement Agreement, the DEA registrations for certain McKesson Distribution Centers are suspended for certain periods of time on a staggered basis.

3. Respondent distributes controlled substances into the state of Idaho.

4. Under the Settlement Agreement, the DEA registration for Respondent is suspended for two years, effective from January 17, 2017 to January 17, 2019.

5. The Settlement Agreement contained a partial exception to the suspension imposed upon Respondent which permits this center, at its option, to possess and distribute controlled substances to federal customers which purchase controlled substances from McKesson under an exclusive contract with the U.S. Department of Veterans Affairs ("VA").

AND WHEREAS, nothing in the Settlement Agreement limits the Board's authority to initiate administrative proceedings under Idaho laws and rules with respect to McKesson's conduct covered by the terms of the Settlement Agreement.

Good cause being shown therefor, it is now hereby ORDERED:

1. This Order amends and replaces the Order Restricting Controlled Substance Registration issued by the Board on May 3, 2017.

2. Respondent's Controlled Substance Registration No. D581 is suspended for two years, effective from the date of this Order through January 17, 2019, or for such other dates as the DEA implements in its suspension. Respondent will notify the Board if the DEA suspension dates are changed. This suspension shall not apply to or limit Respondent's authority to distribute, or operations involving, List 1 Chemical products at or from Respondent which are authorized under Respondent's DEA registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the VA.

3. Failure to comply with any of the terms of this Order may result in additional action being taken against Respondent's controlled substance registration.

DATED this 29th day of June, 2017.

IDAHO BOARD OF PHARMACY

BY: _____

Alex J. Adams, PharmD, MPH
Executive Director

NOTICE OF DUE PROCESS RIGHTS

This is a final order of the Board. Any party may file a motion for reconsideration of this final order within 14 days of the issuance of this order. The Board will dispose of the petition for reconsideration within 21 days of its receipt, or the petition will be considered denied by operation of law. *See* Idaho Code § 67-5246(4) and IDAPA 04.11.01.740.

Pursuant to Idaho Code §§ 67-5270 and 67-5272, any party aggrieved by this final order or orders previously issued in this case may appeal this final order and all previously issued orders in this case to district court by filing a petition in the district court of the county in which:

a. A hearing was held;
b. The final Board action was taken;
c. The party seeking review of the order, resides; or
d. The real property or personal property that was the subject of the Board action is located.

An appeal must be filed within 28 days of (a) the service date of this final order, (b) an order denying petition for reconsideration, or (c) the failure within 21 days to grant or deny a petition for reconsideration, whichever is later. *See* Idaho Code § 67-5273. The filing of an appeal to district court does not itself stay the effectiveness or enforcement of the order under appeal.

[The remainder of this page is intentionally blank.]

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 29th day of June, 2017, I caused to be served a true and correct copy of the foregoing AMENDED ORDER RESTRICTING CONTROLLED SUBSTANCE REGISTRATION by the following method to:

Susan Brichler Trujillo
Quarles & Brady, LLP
Counsel for McKesson Corporation
Renaissance One
Two North Central Avenue
Phoenix, AZ 85004-2391

☒ U.S. Mail
☐ Hand Delivery
☒ Certified Mail, Return Receipt Requested
☐ Overnight Mail
☐ Facsimile:

Nicholas Davis
McKesson Corporation
[redacted]Plymouth Road
Livonia, MI 48150

☒ U.S. Mail
☐ Hand Delivery
☒ Certified Mail, Return Receipt Requested
☐ Overnight Mail
☐ Facsimile:

Carl J. Withroe
Deputy Attorney General
Civil Litigation Division
P. O. [redacted]
Boise, ID 83720-0010

☐ U.S. Mail
☐ Hand Delivery
☐ Overnight Mail
☐ Facsimile:
☒ Email: [redacted]

Ellen Mitchell
Investigations Support Coordinator

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

[redacted]

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MCKESSON CORPORATION, REGISTRATION NO. WHI 6034,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and McKesson Corporation ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2017-258, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to provisions of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2016).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 11, 2006, being issued registration number WHI 6034, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is [redacted], Aurora, CO 80011.

4. Respondent Outlet admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.

5. In January 2017, Respondent Outlet entered into a Settlement Agreement and Release with the United States, acting through the Department of Justice, and on behalf of the Drug Enforcement Administration ("Settlement Agreement"), for not identifying or reporting to the DEA certain orders placed by certain pharmacies which should have been detected by Respondent Outlet as suspicious based on the guidance contained in Drug Enforcement Administration letters dated September 27, 2006, February 7, 2007, and December 27, 2007, about the requirements set forth in 21 C.F.R §1301.74(b) and 21 U.S.C. §842(a)(5).

6. Disposition of the Settlement Agreement included a settlement payment to the United States of $150,000,000.00 and a three-year suspension of Respondent Outlet's Drug Enforcement Administration registration. The suspension of Respondent Outlet's Drug Enforcement Administration registration violates section 12-42.5-123(1)(s), C.R.S.

7. Respondent Outlet was previously disciplined by the Board for occurrences unrelated to the occurrences that led to the Settlement Agreement, as follows:

   a. On or about May 24, 2011, Respondent Outlet entered into a Stipulation and Final Agency Order with the Board in Case No. [redacted] for not timely submitting to the Board a change-in-designated-representative application and fee. Disposition included a $5,000.00 fine.

   b. On or about July 28, 2009, Respondent Outlet entered into a Stipulation and Final Agency Order with the Board in Case No [redacted] for procuring prescription drugs from unregistered sources. Disposition included a $45,000.00 fine.

8. Respondent Outlet admits that its conduct, as set forth above, constitutes a violation of the following sections of the Colorado Revised Statutes and provides grounds for disciplinary action against Respondent Outlet's Colorado registration as a prescription drug outlet:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline. (1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(s) Has had his or her federal registration to manufacture, distribute, or dispense a controlled substance suspended or revoked.

12-42.5-124. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that the applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

9. The Board finds and concludes, and Respondent Outlet agrees, that based upon Respondent Outlet's above-described violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

DISPOSITION

10. **Fine with Surcharge**. Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of Forty Five Thousand Dollars and No Cents ($45,000.00) Respondent Outlet understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of Fifty One Thousand Seven Hundred Fifty Dollars and No Cents ($51,750.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board. Respondent Outlet shall write its registration number (WHI 6034) and the case number ([redacted]) on the check.

11. **Probation**. Respondent Outlet's registration shall be placed on probation for a period of three (3) years. Credit toward satisfying the period of probation shall be given only during such periods of time that Respondent Outlet is in total compliance with all provisions of this Final Agency Order.

12. **Other Requirements**. Through its undersigned Authorized Representative, Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order and probation, Respondent Outlet shall:

    a. promptly pay all its own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmaceuticals and pharmacists in the State of Colorado.

13. **Violations**. Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Completion of Terms**. Respondent Outlet must make a written request to the Board to end the terms and conditions of this Final Agency Order. In any request, it shall be Respondent Outlet's sole responsibility to establish, through written and other documentation, that Respondent Outlet has met all terms of this Final Agency Order. Respondent Outlet's probation shall continue until the Board or its designated authority has verified that Respondent Outlet has completed all terms of

this Final Agency Order. The Board will consider Respondent Outlet's request during the ordinary course of business.

15. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;

    b. To respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. To appeal this Board order.

    Respondent Outlet freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

16. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

17. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

18. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

19. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative.

20. **Effective Date.** This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby

consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

Timothy W Pawlak Sr. VP Dated: 8-25-17
Authorized Representative / Title

Subscribed and sworn to before me in the County of Snohomish, State of Washington, this 25 day of August, 2017, by Timothy W Pawlak, in his/her capacity as an authorized agent of McKesson Corporation.

Notary Public
State of Washington
DAWN M SKIBA
My Appointment Expires Nov 29, 2018

Dawn M Skiba
Notary Public

My commission expires:

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 5th day of September, 2017.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within fully executed **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 5th day of SEPTEMBER 2017, addressed as follows:

By electronic mail to Respondent:
McKesson Corporation
Attn: Wholesaler Manager
[redacted]39th Ave.
Aurora, CO 80011
Email: [redacted]

By electronic mail to Respondent's counsel:
Roger Morris, Esq.
Nick Meza, Esq.
Quarles & Brady LLP
[redacted]

Agent of the Board

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov

November 15, 2017

Susan Brichler Trujillo
Quarles & Brady, LLC
Renaissance One, Two North Central Avenue
Phoenix, AZ 85004-2391

RE: [redacted] **– McKesson & McKesson Corp.**

Dear Ms. Trujillo:

Please find the enclosed Board Orders issued by the Louisiana Board of Pharmacy this week in the above referenced matters.

Sincerely,

Carlos M. Finalet, III
General Counsel

Pharmacy Program
Tel. 225.922.0852
Fax. 225.925.6499

CDS Program
Tel. 225.925.4770
Fax. 225.925.6499

PMP Office
Tel. 225.925.4767
Fax. 225.925.6408

Executive Office
Tel. 225.925.6496
Fax. 225.922.0316

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

MCKESSON CORPORATION **Case No.** [redacted]

LOUISIANA CONTROLLED DANGEROUS SUBSTANCE LICENSE NO. [redacted]

****

CONSENT AGREEMENT

WHEREAS, the federal DEA license belonging to MCKESSON CORPORATION (hereinafter referred to as "Respondent"), LOUISIANA CONTROLLED DANGEROUS SUBSTANCE LICENSE NO. 31429, 38220 Plymouth Road, Livonia, MI 48150-1050, is suspended from June 29, 2017 to January 17, 2019.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

1. **LOUISIANA CONTROLLED DANGEROUS SUBSTANCE LICENSE NO. 31429 belonging to MCKESSON CORPORATION is hereby suspended from June 29, 2017 to January 17, 2019 or for such other dates as the DEA implements in its suspension.**

2. **This suspension shall not apply to or limit Respondent's authority to distribute, or operations involving, List 1 Chemical products at or from Respondent which are authorized under Respondent's DEA registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the U.S. Department of Veterans Affairs.**

3. **Respondent to reimburse the Board $250.00 for administrative costs, to be paid simultaneously with the execution of this Consent Agreement by Respondent.**

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter and waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to provide the Board with the following for reporting purposes to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB):

Respondent's National Provider Identifier (NPI) Number: _____

Medicare Provider Number (if in the possession of one): _____

I, Scott Miller, authorized to act on behalf of and acting on behalf of **MCKESSON CORPORATION, CDS.031429,** understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

SIGNED, AGREED TO AND ENTERED ON THIS 17th DAY OF October, 2017.

MCKESSON CORPORATION, 38220 Plymouth Road, Livonia, MI 48150-1050

BY: Authorized Representative

ROGER MORRIS
Quarles & Brady, LLP
Renaissance One
Two North Central Avenue
Phoenix, AZ 85004-2391

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on November 15, **2017**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Carl W. Aron

Carl W. Aron
President and Hearing Officer for the Board

RECEIVED
NOV 20 2017
NH BOARD OF PHARMACY

State of New Hampshire
Board of Pharmacy
Concord, New Hampshire

In the Matter of:
McKesson Drug Company
License No. 3978
(Misconduct Allegations)

SETTLEMENT AGREEMENT

In order to avoid the delay and expense of further proceedings and to promote the best interests of the public and the practice of pharmacy, the New Hampshire Board of Pharmacy ("Board") and McKesson Drug Company ("McKesson" or "Respondent"), a Manufacturer/Wholesaler/Distributor/Broker licensed by the Board, do hereby stipulate and agree to resolve certain allegations of professional misconduct now pending before the Board according to the following terms and conditions:

1. Pursuant to RSA 318:29, I; 318:30; and 318:31, and Pharmacy Administrative Rule ("Ph") 204, the Board has jurisdiction to investigate and adjudicate allegations of professional misconduct committed by pharmacists. Pursuant to RSA 318:30, VII, 318:31, IV and Ph 204.15, the Board may, at any time, dispose of such allegations by settlement and without commencing a disciplinary hearing.
2. The Board first granted Respondent a license to practice as a Manufacturer/Wholesaler/Distributor/Broker in the State of New Hampshire on April 5, 1999. Respondent holds license number 3978. Respondent operates as a Manufacturer/Wholesaler/Distributor/Broker in Livonia, Michigan.
3. On or about January 17, 2017, Respondent notified the Board that it had entered into a settlement agreement with the United States, acting through the U.S. Department of

Justice ("DOJ") dated effective January 17, 2017, which attached terms and conditions set forth in the Administrative Memorandum of Agreement dated effective January 17, 2017 (collectively, the "DEA Settlement Agreement").

4. Under the DEA Settlement Agreement, the DEA registration for Respondent's Livonia distribution facility is suspended for two years, effective January 18, 2017, to January 18, 2019.

5. The DEA Settlement Agreement permits the Livonia distribution facility to distribute and possess List I Chemicals Products and contains a partial exception to the suspension imposed upon Respondent which permits the Livonia distribution center, at its option, to possess and distribute controlled substances to federal customers which purchase controlled substances from McKesson under an exclusive contract with the U.S. Department of Veterans Affairs ("VA").

6. On or about March 24, 2017, Respondent notified the Board that it had been subject to disciplinary action in New York as a result of the DEA Settlement Agreement.

7. On or about July 17, 2017, Respondent notified the Board that it had been subject to disciplinary action in Idaho as a result of the DEA Settlement Agreement it had entered into with the DEA.

8. Respondent stipulates that if a disciplinary hearing were to take place, Hearing Counsel would prove that Respondent engaged in professional misconduct, in violation of RSA 318:29, II, (c) and RSA 318:29-b, I, by being subjected to a disciplinary action in Idaho and by entering into a Settlement Agreement with the DEA.

9. The Board finds that Respondent committed the acts as described above and concludes that, by engaging in such conduct, Respondent violated RSA 318:29, II, (c).

10. Respondent acknowledges that this conduct constitutes grounds for the Board to impose disciplinary sanctions against Respondent's license to practice as a Manufacturer/Wholesaler/Distributor/Broker in the State of New Hampshire.

11. Respondent consents to the Board imposing the following discipline, pursuant to RSA 318:29, IV, and 318:55.

A. Respondent is reprimanded.

B. Respondent's right to distribute controlled substances is suspended until January 17, 2019, or for such other period of time as the DEA implements in its suspension. Respondent will notify the Board if the DEA suspension dates are changed. This suspension shall not apply to or limit Respondent's authority to distribute, or operations involving List I Chemical Products at or from Respondent which are authorized under Respondent's DEA registration and the DEA Settlement Agreement. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers which purchase controlled substances from McKesson under an exclusive contract with the VA.

C. Respondent is assessed an administrative fine in the amount of $1,000. Respondent shall pay this total amount in full within thirty (30) days of the effective date of this *Settlement Agreement*, as defined further below, by

delivering a money order or bank check, made payable to "Treasurer, State of New Hampshire," to the Board's office at 121 South Fruit Street, Concord, New Hampshire 03301.

D. The Board may consider Respondent's compliance with the terms and conditions herein in any subsequent proceeding before the Board regarding Respondent's license.

12. Respondent's breach of any terms or conditions of this *Settlement Agreement* shall constitute unprofessional conduct pursuant to RSA 318:29, II (c), and shall be a separate and sufficient basis for further action by the Board.

13. Except as provided herein, this *Settlement Agreement* shall bar the commencement of further disciplinary action by the Board based upon the misconduct described above or any subsequent reciprocal state action based on the DEA Settlement Agreement. However, the Board may consider the fact that discipline was imposed by this *Settlement Agreement* as a factor in determining appropriate discipline should any further misconduct be proven against Respondent in the future.

14. This *Settlement Agreement* shall become a permanent part of Respondent's file, which is maintained by the Board as a public document.

15. Respondent voluntarily enters into and signs this *Settlement Agreement* and states that no promises or representations have been made to it other than those terms and conditions expressly stated herein.

16. The Board agrees that in return for Respondent executing this *Settlement Agreement*, the Board will not proceed with further disciplinary action against Respondent in the

event that Respondent is subject to reciprocal discipline in another state imposed solely in connection with the DEA Settlement Agreement and/or another state's discipline based on the DEA Settlement Agreement.

17. The Board agrees that in return for Respondent executing this *Settlement Agreement*, the Board will not proceed with the formal adjudicatory process based upon the facts described herein.

18. Respondent understands that its action in entering into this *Settlement Agreement* is a final act and not subject to reconsideration or judicial review or appeal.

19. Respondent has had the opportunity to seek and obtain the advice of an attorney of its choosing in connection with its decision to enter into this *Settlement Agreement*.

20. Respondent understands that the Board must review and accept the terms of this *Settlement Agreement*. If the Board rejects any portion, the entire *Settlement Agreement* shall be null and void. Respondent specifically waives any claims that any disclosures made to the Board during its review of this *Settlement Agreement* have prejudiced its right to a fair and impartial hearing in the future if this *Settlement Agreement* is not accepted by the Board.

21. Respondent certifies that it has read this document titled *Settlement Agreement*. Respondent understands that it has the right to a formal adjudicatory hearing concerning this matter and that at said hearing it would possess the rights to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its own behalf, to contest the allegations, to present oral argument, and to appeal to the courts. Further, Respondent fully understands the nature, qualities and dimensions of

these rights. Respondent understands that by signing this *Settlement Agreement*, it waives these rights as they pertain to the misconduct described herein.

22. This *Settlement Agreement* shall take effect as a Final Order of the Board on the date it is signed by an authorized representative of the Board.

FOR THE RESPONDENT

Date: 11.7.2017

McKesson Drug Company
Respondent

Date: 11/7/2017

Roger Morris, Esq.
Counsel for Respondent

FOR THE BOARD/*

This proceeding is hereby terminated in accordance with the binding terms and conditions set forth above.

Date: 12/12/17

(Signature)

Michael D Bilek

(Print or Type Name)
Authorized Representative of the
New Hampshire Board of Pharmacy

/* Board members, did not participate:

RECEIVED
NOV 20 2017
NH BOARD OF PHARMACY

State of New Hampshire
Board of Pharmacy
Concord, New Hampshire

In the Matter of:
McKesson Drug Company
License No. 2831
(Misconduct Allegations)

SETTLEMENT AGREEMENT

In order to avoid the delay and expense of further proceedings and to promote the best interests of the public and the practice of pharmacy, the New Hampshire Board of Pharmacy ("Board") and McKesson Drug Company ("McKesson" or "Respondent"), a Manufacturer/Wholesaler/Distributor/Broker licensed by the Board, do hereby stipulate and agree to resolve certain allegations of professional misconduct now pending before the Board according to the following terms and conditions:

1. Pursuant to RSA 318:29, I; 318:30; and 318:31, and Pharmacy Administrative Rule ("Ph") 204, the Board has jurisdiction to investigate and adjudicate allegations of professional misconduct committed by pharmacists. Pursuant to RSA 318:30, VII, 318:31, IV and Ph 204.15, the Board may, at any time, dispose of such allegations by settlement and without commencing a disciplinary hearing.
2. The Board first granted Respondent a license to practice as a Manufacturer/Wholesaler/Distributor/Broker in the State of New Hampshire on November 25, 1995. Respondent holds license number 2831. Respondent operates as a Manufacturer/Wholesaler/Distributor/Broker in Washington Court House, Ohio.
3. On or about January 17, 2017, Respondent notified the Board that it had entered into a settlement agreement with the United States, acting through the U.S. Department of

Justice ("DOJ") dated effective January 17, 2017, which attached terms and conditions set forth in the Administrative Memorandum of Agreement dated effective January 17, 2017 (collectively, the "DEA Settlement Agreement").

4. Under the DEA Settlement Agreement, the DEA registration for Respondent's Washington Court House distribution facility is suspended for two years, effective January 18, 2019, to January 18, 2021.

5. The DEA Settlement Agreement permits the Washington Court House distribution facility to distribute and possess List I Chemicals Products and contains a partial exception to the suspension imposed upon Respondent that permits the Washington Court House distribution center, at its option, to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson under an exclusive contract with the U.S. Department of Veterans Affairs ("VA").

6. On or about July 17, 2017, Respondent notified the Board that it had been subject to disciplinary action in Idaho as a result of the DEA Settlement Agreement it had entered into with the DEA.

7. Respondent stipulates that if a disciplinary hearing were to take place, Hearing Counsel would prove that Respondent engaged in professional misconduct, in violation of RSA 318:29, II, (c) and RSA 318:29-b, I, by being subjected to a disciplinary action in Idaho and by entering into a Settlement Agreement with the DEA.

8. The Board finds that Respondent committed the acts as described above and concludes that, by engaging in such conduct, Respondent violated RSA 318:29, II, (c).

9. Respondent acknowledges that this conduct constitutes grounds for the Board to impose disciplinary sanctions against Respondent's license to practice as a Manufacturer/Wholesaler/Distributor/Broker in the State of New Hampshire.

10. Respondent consents to the Board imposing the following discipline, pursuant to RSA 318:29, IV, and 318:55.

    A. Respondent is reprimanded.

    B. Respondent's right to distribute controlled substances is suspended effective January 18, 2019 until January 18, 2021, or for such other dates as the DEA implements in its suspension. Respondent will notify the Board if the DEA suspension dates are changed. This suspension shall not apply to or limit Respondent's authority to distribute, or operations involving, List I Chemical Products at or from Respondent that are authorized under Respondent's DEA registration and the DEA Settlement Agreement. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson under an exclusive contract with the VA.

    C. Respondent is assessed an administrative fine in the amount of $1,000. Respondent shall pay this total amount in full within thirty (30) days of the effective date of this *Settlement Agreement*, as defined further below, by

delivering a money order or bank check, made payable to "Treasurer, State of New Hampshire," to the Board's office at 121 South Fruit Street, Concord, New Hampshire 03301.

D. The Board may consider Respondent's compliance with the terms and conditions herein in any subsequent proceeding before the Board regarding Respondent's license.

11. Respondent's breach of any terms or conditions of this *Settlement Agreement* shall constitute unprofessional conduct pursuant to RSA 318:29, II (c), and shall be a separate and sufficient basis for further action by the Board.

12. Except as provided herein, this *Settlement Agreement* shall bar the commencement of further disciplinary action by the Board based upon the misconduct described above or any subsequent reciprocal state action based on the DEA Settlement Agreement. However, the Board may consider the fact that discipline was imposed by this *Settlement Agreement* as a factor in determining appropriate discipline should any further misconduct be proven against Respondent in the future.

13. This *Settlement Agreement* shall become a permanent part of Respondent's file, which is maintained by the Board as a public document.

14. Respondent voluntarily enters into and signs this *Settlement Agreement* and states that no promises or representations have been made to it other than those terms and conditions expressly stated herein.

15. The Board agrees that in return for Respondent executing this *Settlement Agreement*, the Board will not proceed with the formal adjudicatory process based upon the facts described herein.

16. The Board agrees that in return for Respondent executing this *Settlement Agreement*, the Board will not proceed with further disciplinary action against Respondent in the event that Respondent is subject to reciprocal discipline in another state imposed solely in connection with the DEA Settlement Agreement and/or another state's discipline based on the DEA Settlement Agreement.

17. Respondent has had the opportunity to seek and obtain the advice of an attorney of its choosing in connection with its decision to enter into this *Settlement Agreement*.

18. Respondent understands that the Board must review and accept the terms of this *Settlement Agreement*. If the Board rejects any portion, the entire *Settlement Agreement* shall be null and void. Respondent specifically waives any claims that any disclosures made to the Board during its review of this *Settlement Agreement* have prejudiced its right to a fair and impartial hearing in the future if this *Settlement Agreement* is not accepted by the Board.

19. Respondent certifies that it has read this document titled *Settlement Agreement*. Respondent understands that it has the right to a formal adjudicatory hearing concerning this matter and that at said hearing it would possess the rights to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its own behalf, to contest the allegations, to present oral argument, and to appeal to the courts. Further, Respondent fully understands the nature, qualities and dimensions of

these rights. Respondent understands that by signing this *Settlement Agreement*, it waives these rights as they pertain to the misconduct described herein.

20. This *Settlement Agreement* shall take effect as a Final Order of the Board on the date it is signed by an authorized representative of the Board.

FOR THE RESPONDENT

Date: 11.7.2017

McKesson Drug Company
Respondent

Date: 11/7/2017

Roger Morris, Esq.
Counsel for Respondent

FOR THE BOARD/*

This proceeding is hereby terminated in accordance with the binding terms and conditions set forth above.

Date: 12/12/17

(Signature)

Michael D. Bullock

(Print or Type Name)
Authorized Representative of the
New Hampshire Board of Pharmacy

/* Board members, did not participate:

BEFORE THE IOWA BOARD OF PHARMACY

RE: Application for Controlled Substances Act (CSA) Registration of **MCKESSON CORPORATION,** Wholesale Drug License No. 5772 Applicant.	**REGISTRATION BY CONSENT AGREEMENT**

COME NOW the Iowa Board of Pharmacy ("Board") and McKesson Corporation d/b/a McKesson Drug Company ("Applicant"), 38220 Plymouth Road, Livonia MI 48150, and enter into this Registration by Consent Agreement ("Agreement") pursuant to Iowa Code sections 17A.10 and 17A.18. The Board has jurisdiction over Applicant and the subject matter of this case pursuant to Iowa Code chapters 17A, 124, and 272C (2018), and 657 IAC chapter 10.

A. FACTUAL CIRCUMSTANCES

1. On November 30, 2017, the Board received an application for a CSA registration from Applicant.

2. Applicant disclosed a two year suspension of its federal Drug Enforcement Administration (DEA) registration pursuant to a Settlement Agreement and Release and Administrative Memorandum of Agreement ("Memorandum of Agreement") entered into with the U.S. Department of Justice, DEA. The suspension is effective from January 17, 2017 through January 17, 2019, but allows Applicant to distribute controlled substances to federal customers pursuant to its exclusive contract with the U.S. Department of Veterans Affairs. The settlement does not apply to or limit Applicant's authority to distribute, or operations involving, List I Chemical products at or from Applicant which are authorized under the Applicant's DEA registration.

B. LEGAL GROUNDS

3. The Board shall register an applicant unless it determines that the issuance of a registration would be inconsistent with the public interest. *See* Iowa Code section 124.303(1).

4. In determining the public interest, the board shall consider the suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law. *See* Iowa Code section 124.303(1)(f).

C. REGISTRATION BY CONSENT

5. Applicant admits the allegations in the Factual Circumstances and acknowledges that the allegations, if proven in a contested case hearing concerning registration denial, would constitute grounds for the adverse action agreed to in this Agreement.

6. Execution of this Agreement constitutes the resolution of a contested case. Applicant has a right to hearing before the Board on the grounds for license denial, but Applicant waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Agreement. Once entered, this Agreement shall have the force and effect of a Board Order entered following a contested case hearing concerning license denial.

7. Applicant acknowledges that it has the right to be represented by counsel on this matter.

8. This Agreement is subject to approval by a majority of the full Board. If the Board does not approve this Agreement, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

9. This Agreement shall be part of Applicant's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

10. Applicant understands that this Agreement constitutes adverse action and that the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

11. This Agreement, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

12. The Board's approval of this Agreement shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

13. Applicant shall be issued an Iowa CSA registration.

14. Applicant's CSA registration is hereby **RESTRICTED** for the duration of the suspension of Applicant's DEA registration, which is expected to last until January 17, 2019. Applicant's restriction on its CSA registration shall mirror the restrictions on Applicant's DEA registration during the period of suspension. This Agreement is intended to mirror the Settlement Agreement and Release and Memorandum of Agreement with the DEA. If any restrictions are added or removed by the DEA, including but not limited to an early termination of the DEA suspension, those changes shall be incorporated into this Agreement.

15. Any changes to the terms or conditions on Applicant's DEA registration shall be promptly reported to the Iowa Board of Pharmacy.

16. Should Applicant violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 124 and 272C and 657 IAC chapter 10.

This Registration by Consent Agreement is voluntarily submitted by Applicant to the Board for its consideration on the ___ day of _____, 2018.

Ammie McAsey

McKesson Corporation
Wholesale Drug License No. 5772
Applicant

By the signature above, Ammie McAsey acknowledges s/he is the Senior Vice President, U.S. Pharma Distribution Operations for Applicant and is authorized to sign this Registration by Consent Agreement on behalf of Applicant.

This Registration by Consent Agreement is approved by the Iowa Board of Pharmacy on the 14 day of March, 2018.

Chairperson
Iowa Board of Pharmacy

BEFORE THE IOWA BOARD OF PHARMACY

RE: Controlled Substances Act Registration of **MCKESSON DRUG COMPANY** Registration No. [redacted] Respondent	CASE NO [redacted] **TERMINATION ORDER**

Respondent has been released from the Memorandum of Agreement with the DEA described in the Board Order in the above-captioned case dated March 14, 2018.

IT IS THEREFORE ORDERED that the restriction placed on Respondent's registration is terminated. Respondent's Iowa registration is returned to its full privileges, free and clear of all restrictions.

Dated this 22nd day of February, 2021.

Andrew Funk, Pharm.D., Executive Director
IOWA BOARD OF PHARMACY

IOWA BOARD OF PHARMACY

400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
515/281-5944 FAX 515/281-4609
https://pharmacy.iowa.gov

CSA 2021

CERTIFICATE OF REGISTRATION

IOWA CONTROLLED SUBSTANCES ACT

REGISTRATION NUMBER **2210426**
DRUG SCHEDULES REGISTERED **22N33N45**

REGISTRATION ISSUED **03/11/2020**
REGISTRATION EXPIRES **12/31/2021**
REGISTRATION STATUS: **Current/Active**

NAME, MAILING ADDRESS
McKesson Drug Company
3000 Kenskill Ave
Washington OH 43160

NAME, REGISTERED LOCATION
McKesson Drug Company
3000 Kenskill Ave
Washington OH 43160

Distributor

Todd Spaulding , Responsible Individual

COUNTY 0 Outside Iowa

DEA REGISTRATION NO. RM0220688

1008

BEFORE THE IOWA BOARD OF PHARMACY

RE: Application for Controlled Substances Act (CSA) Registration of **MCKESSON CORPORATION,** Wholesale Drug License No. 5037 Applicant.	**REGISTRATION BY CONSENT AGREEMENT**

COME NOW the Iowa Board of Pharmacy ("Board") and McKesson Corporation d/b/a McKesson Drug Company ("Applicant"), [redacted] Kenskill Avenue, Washington Court House OH 43160, and enter into this Registration by Consent Agreement ("Agreement") pursuant to Iowa Code sections 17A.10 and 17A.18. The Board has jurisdiction over Applicant and the subject matter of this case pursuant to Iowa Code chapters 17A, 124, and 272C (2018), and 657 IAC chapter 10.

A. FACTUAL CIRCUMSTANCES

1. On November 30, 2017, the Board received an application for a CSA registration from Applicant.

2. Applicant disclosed a two year suspension of its federal Drug Enforcement Administration (DEA) registration pursuant to a Settlement Agreement and Release and Administrative Memorandum of Agreement ("Memorandum of Agreement") entered into with the U.S. Department of Justice, DEA. The suspension is effective from January 18, 2019 through January 18, 2021, but allows Applicant to distribute controlled substances to federal customers pursuant to its exclusive contract with the U.S. Department of Veterans Affairs. The settlement does not apply to or limit Applicant's authority to distribute, or operations involving, List I Chemical products at or from Applicant which are authorized under the Applicant's DEA registration.

B. LEGAL GROUNDS

3. The Board shall register an applicant unless it determines that the issuance of a registration would be inconsistent with the public interest. *See* Iowa Code section 124.303(1).

4. In determining the public interest, the board shall consider the suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law. *See* Iowa Code section 124.303(1)(f).

C. REGISTRATION BY CONSENT

5. Applicant admits the allegations in the Factual Circumstances and acknowledges that the allegations, if proven in a contested case hearing concerning registration denial, would constitute grounds for the adverse action agreed to in this Agreement.

6. Execution of this Agreement constitutes the resolution of a contested case. Applicant has a right to hearing before the Board on the grounds for license denial, but Applicant waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Agreement. Once entered, this Agreement shall have the force and effect of a Board Order entered following a contested case hearing concerning license denial.

7. Applicant acknowledges that it has the right to be represented by counsel on this matter.

8. This Agreement is subject to approval by a majority of the full Board. If the Board does not approve this Agreement, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

9. This Agreement shall be part of Applicant's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

10. Applicant understands that this Agreement constitutes adverse action and that the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

11. This Agreement, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

12. The Board's approval of this Agreement shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

13. Applicant shall be issued an Iowa CSA registration.

14. Applicant's CSA registration shall be **RESTRICTED** for the duration of the suspension of Applicant's DEA registration, which is expected to last from January 18, 2019, through January 18, 2021. Applicant's restrictions on its CSA registration shall mirror the restrictions on Applicant's DEA registration during the period of suspension. This Agreement is intended to mirror the Settlement Agreement and Release and Memorandum of Agreement with the DEA. If any restrictions are added or removed by the DEA, including but not limited to an early termination of the DEA registration suspension, those changes shall be incorporated into this Agreement.

15. Any changes to the terms or conditions on Applicant's DEA registration shall be

promptly reported to the Iowa Board of Pharmacy.

16. Should Applicant violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 124 and 272C and 657 IAC chapter 10.

This Registration by Consent Agreement is voluntarily submitted by Applicant to the Board for its consideration on the ___ day of _____, 2018.

Ammie McAsey

McKesson Corporation
Wholesale Drug License No. 5037
Applicant

By the signature above, Ammie McAsey acknowledges s/he is the Senior Vice President, U.S. Pharma Distribution Operations for Applicant and is authorized to sign this Registration by Consent Agreement on behalf of Applicant.

This Registration by Consent Agreement is approved by the Iowa Board of Pharmacy on the 14 day of March, 2018.

Chairperson
Iowa Board of Pharmacy

IN THE MATTER OF	*	**BEFORE THE MARYLAND STATE**
McKESSON CORPORATION **300 Kendall Avenue** **Washington Court House, Ohio**	*	**BOARD OF PHARMACY**
PERMIT NO. D00811	*	***Case No.** [redacted]

* * * * * * * * * * * * *

CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") received self-reports from McKesson Corporation ("Respondent-Distributor") that it had entered into a settlement agreement with the U.S. Department of Justice ("DOJ") in which the DEA registration for the Respondent-Distributor's Washington Court House Ohio location was suspended for two (2) years, effective from January 18, 2019 to January 18, 2021. The Respondent-Distributor also self-reported subsequent disciplinary actions imposed by other state boards primarily based on the Respondent's Settlement Agreement with the DOJ.

In lieu of instituting formal proceedings against McKesson Corporation., in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 et seq., the Board and McKesson Corporation, have agreed to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

1. On or about December 26, 1996, the Respondent was issued a distributor permit to operate in Maryland under Permit Number [redacted]. The Respondent's permit is active and will expire on May 31, 2019.

2. The Respondent-Distributor is located in Washington Court House, Ohio, and distributes prescription drugs, including controlled dangerous substances, into Maryland.

3. On or about January 17, 2017, the Respondent-Distributor entered into a Settlement Agreement with the U.S. Department of Justice ("DOJ") based on the DOJ' s contention that McKesson failed to properly monitor its sales of controlled substances; failed to conduct adequate due diligence and keep accurate records of its sales; failed to maintain effective controls against diversion of particular controlled substances into channels other than legitimate medical, scientific and industrial channels; and failed to report suspicious orders of controlled substances to the U.S. Drug Enforcement Administration ("DEA").

4. Twelve (12) McKesson distribution centers were referenced in the Settlement Agreement, including the distribution center located in Washington Court House, Ohio.

5. Under the terms of the Settlement Agreement, the DEA registrations issued to the Aurora, Livonia, and Washington Court House distribution centers were suspended for certain periods of time on a staggered basis. Specifically, the DEA registration issued to the Respondent-Distributor's Washington Court House distribution center is suspended from January 18, 2019, to January 18, 2021, with the exceptions that the Respondent may possess and distribute controlled substances to federal customers which purchase controlled substances from the Respondent-Distributor under an exclusive contract with the U.S. Department of Veterans Affairs. In addition, the suspension does not apply to or limit Respondent-Distributor's

authority to distribute, or operations involving, List 1 Chemical products at or from Respondent-Distributor's Washington Court House distribution center.

6. Subsequent to the effective date of the Settlement Agreement, the Board was notified that the following state boards of pharmacy took action essentially mirroring the restrictions imposed by the Settlement Agreement: Idaho Board of Pharmacy, Louisiana Board of Pharmacy, and the New Hampshire Board of Pharmacy.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that McKesson Corporation, Permit Number D00811, is subject to discipline in accordance with Md. Code Ann., Health Occ. § 12-601 and COMAR 10.34.22.05A(3)(v).

ORDER

Based upon an affirmative vote of a majority of the Board, in accordance with Health Occ. Art. § 12-204, it this 20th day of March, 2018, hereby,

ORDERED that McKesson Corporation, Permit No. D00811, shall be prohibited from distributing controlled dangerous substances into Maryland effective January 18, 2019, to January 18, 2021. If the effective suspension dates in the DOJ Settlement Agreement referenced herein for the Washington Court House distribution center are changed, the Respondent-Distributor shall immediately notify the Board of such change and the change will automatically be incorporated into this Order without the need for further Board action or approval; and be it further,

ORDERED that the prohibition above does not apply to or limit the Respondent-Distributor's authority to distribute, or operations involving, List I Chemical Products at or from the Respondent-Distributor that are authorized under the Respondent's DEA registration and the DEA Settlement Agreement. The Respondent-Distributor is also permitted, at its option, to possess

and distribute controlled substances to federal customers that purchase controlled substances form the Respondent-Distributor under an exclusive contract with the VA; and be it further,

ORDERED the Respondent-Distributor shall comply with all laws and regulations governing the operation of a wholesale distributor in the State of Maryland, to include federal and State laws governing the proper handling and distribution of controlled dangerous substances; and be it further,

ORDERED that in the event the Respondent-Distributor violates any terms of this Order, the Board, after notice and an opportunity for a hearing, and a determination of a violation, impose any disciplinary sanction it deems appropriate, including suspension, revocation, and fines, said violation being proven by a preponderance of the evidence; and be it further,

ORDERED that this is a final order and as such is a public document pursuant to Md. Code Ann., General Provisions Article§ 4-333.

3-20-18
Date

Deena Speights-Napata
Deena Speights-Napata,
Executive Director for:

Mitra Gavgani, Pharm d.
Board President

CONSENT

1. By signing this Consent, McKesson Corporation submits to the foregoing Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.

2. McKesson Corporation acknowledges the validity of this Consent Order as if it were made after a hearing in which it would have had the right to counsel, to confront witnesses, and to all other substantial procedural protections provided by law.

3. McKesson Corporation acknowledges that, by entering into this Consent Order, it is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

4. McKesson Corporation acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

5. McKesson Corporation signs this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. McKesson Corporation fully understands the language, meaning, and effect of this Consent Order.

March 13, 2018
Date

Ammie McAsey

Name: Ammie McAsey

Title: SVP Distribution Operations

STATE OF Mississippi

COUNTY/CITY OF DeSoto

I hereby certify that on this 13 day of , 2018, before me, a Notary Public of the State of and County/City aforesaid, personally appeared and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of McKesson Corporation.

Gloria D. Kinnard
Notary Public
My commission expires: September 5, 2020

GLORIA D KINNARD
NOTARY PUBLIC
ID No. 103360
Commission Expires
Sep 5, 2020
STATE OF MISSISSIPPI
DE SOTO COUNTY

L. MITCHELL JONES (U.S.B. 5979)
Assistant Attorney General
SEAN D. REYES (U.S.B. 7969)
Utah Attorney General
Commercial Enforcement Division
Heber M. Wells Building
Box 140872
Salt Lake City, UT 84114-6741
Telephone: (801) 366-0310

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSE OF **MCKESSON CORPORATION** **D/B/A MCKESSON DRUG COMPANY** UTAH LICENSE #9094524-8913 TO DISPENSE CONTROLLED SUBSTANCES IN THE STATE OF UTAH	))))))	STIPULATION AND ORDER CASE NO. [redacted]

MCKESSON CORPORATION D/B/A MCKESSON DRUG COMPANY ("Respondent") and the **DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING** of the Department of Commerce of the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action. Ammie McAsey is authorized to sign this Stipulation on behalf of Respondent.

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to a hearing, the right to call witnesses on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to all administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-4-901 through R151-4-907. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation and Order, and will release other information about this disciplinary action against Respondent's license, to other persons and entities.

7. Respondent admits the following facts are true:

   a. Respondent was first licensed to dispense controlled substances in the State of Utah on August 14, 2014. Respondent is based in Washington Court House, Ohio.

   b. On or about January 5, 2017, Respondent entered into a "Settlement Agreement and Release" with the U.S. Department of Justice on behalf of the Drug Enforcement Administration, a copy of which is incorporated by reference to this Stipulation and Order and attached as Exhibit A.

   c. On or about January 5, 2017, Respondent entered into an "Administrative Memorandum of Agreement" with the U.S. Department of Justice, Drug Enforcement Administration ("DEA"), a copy of which is incorporated by reference to this Stipulation and Order and attached as Exhibit B.

   d. Pursuant to the terms of the Settlement Agreement and Release and Administrative Memorandum of Agreement, Respondent agreed to the suspension of Respondent's DEA registration from January 18, 2019 to January 18, 2021.

   e. The suspension of the DEA registration described in Exhibits A and B would constitute misconduct in the State of Utah.

   f. Utah Code Ann. § 58-37-6(4)(g) provides that when an individual's DEA registration is suspended, then the Division shall immediately suspend the individual's Utah controlled substance license.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(d); and that said conduct justifies disciplinary action against Respondent's license pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent agrees that an Order, which constitutes disciplinary action against Respondent's licenses by the Division pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2), shall be entered in this matter as follows:

   (a) Respondent's Utah license to distribute controlled substances shall be suspended beginning January 18, 2019, and remain suspended until January 18, 2021, or until the DEA lifts the suspension and re-instates the registration.

(b) The suspension shall not apply to, or limit, Respondent's right to distribute, or engage in operations, involving List 1 chemical products, at or from Respondent, which are permitted under the Settlement Agreement and Release and Administrative Memorandum of Agreement.

(c) The Division's action in this Stipulation and Order does not affect any legal ability or inability of Respondent to possess and distribute controlled substances to federal customers under Respondent's exclusive contract with the U.S. Department of Veterans Affairs.

9. Upon approval by the Director of the Division this Stipulation and Order shall be the final compromise and settlement of this non-criminal administrative matter. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of her having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may subject Respondent to revocation or other sanctions.

13. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

14. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

15. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

DIVISION OF OCCUPATIONAL &
PROFESSIONAL LICENSING

BY: _____
JENNIFER ZAELIT
Bureau Manager

DATE: 4/5/2018

RESPONDENT

BY: _____
AMMIE McASEY

DATE: April 4, 2018

SEAN D. REYES
UTAH ATTORNEY GENERAL

BY: _____
L. MITCHELL JONES
Counsel for the Division

DATE: 5 Apr 18

ORDER

THE ABOVE STIPULATION, in the matter of **MCKESSON CORPORATION, D/B/A MCKESSON DRUG COMPANY,** is hereby approved by the Division of Occupational and Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

DATED this 9 day of April, 2018.

DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

MARK B. STEINAGEL
Director

Investigator: Sharilee McIntyre

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release ("Settlement Agreement" or "Agreement") is entered into between the United States of America, acting through the United States Department of Justice ("DOJ"),[1] and on behalf of the Drug Enforcement Administration ("DEA") (collectively referred to herein as the "United States"), and McKesson Corporation ("McKesson").

II. RECITALS

A. McKesson is a corporation organized and existing under the laws of the State of Delaware. McKesson's corporate headquarters and principal place of business is located at One Post Street, San Francisco, California.

B. McKesson is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. McKesson distributes pharmaceuticals through a network of distribution centers located throughout the United States, including distribution centers located in the following areas: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; La Crosse, Wisconsin; Lakeland, Florida; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California. McKesson formerly distributed pharmaceuticals through a distribution center located in Landover, Maryland, which closed in January 2012 (the "Landover Distribution Center"), and in La Vista, Nebraska, which closed in October 2016. A list of all McKesson U.S. Pharmaceutical distribution

[1] The Department of Justice is represented by the following 12 U.S. Attorney's Offices: Central District of California; Eastern District of California; District of Colorado; Middle District of Florida; Eastern District of Kentucky; Northern District of Illinois; District of Massachusetts; Eastern District of Michigan; District of Nebraska; District of New Jersey; Northern District of West Virginia; and Western District of Wisconsin.

EX A

centers that hold a DEA Certificate of Registration as of the Effective Date of this Agreement is attached hereto as Appendix A. Collectively, the distribution centers listed in Appendix A and the Landover Distribution Center are referred to herein as the "McKesson Distribution Centers."

C. At times relevant to this Agreement, the McKesson Distribution Centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* (the "CSA" or the "Act"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

D. The DEA is the DOJ component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

E. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

F. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. § 1301.74(b).

G. The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. § 1301.74(b). *See* 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

III. COVERED CONDUCT

The United States contends that it has certain civil claims against McKesson under 21 U.S.C. §§ 821, 823, 827, and 842(a)(5) for engaging in the following conduct (the "Covered Conduct") from January 1, 2009, through the Effective Date as that term is defined in Section

VI(F) (the "Covered Time Period"):

A. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations at McKesson Distribution Centers, including the following specific centers:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
La Crosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;
Washington Courthouse, Ohio; and
West Sacramento, California.

B. In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to herein as the "2008 Agreements") arising out of, among other things, McKesson's failure to report suspicious orders of controlled substances to the DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP") in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to the DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b).

C. McKesson failed to follow the procedures and policies set forth in the McKesson

CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP.

D. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers during the Covered Time Period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements.

E. McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined by the DEA in three letters from the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including McKesson, on September 27, 2006, February 7, 2007, and December 27, 2007.

F. Certain McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

IV. ACCEPTANCE OF RESPONSIBILITY

A. On or about September 27, 2006, February 7, 2007, and December 27, 2007, DEA's

Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum. The Compliance Addendum is an attachment to the Administrative Memorandum of Agreement (the "2017 MOA") entered into by McKesson and DEA contemporaneously with this Agreement. The Compliance Addendum and the 2017 MOA are attached hereto as Appendix B.

B. On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided, among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its CSMP. McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to

prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

V. TERMS AND CONDITIONS

In consideration of the mutual promises, covenants, and obligations set forth in this Settlement Agreement, the United States and McKesson agree as follows:

A. McKesson shall pay the United States the sum of One Hundred Fifty Million Dollars ($150,000,000.00) (the "Settlement Amount") within five (5) business days of the Effective Date of this Settlement Agreement, by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the United States.

B. In consideration of the fulfillment of the payment of the Settlement Amount, the United States agrees to:

1. Fully and finally release McKesson and all McKesson facilities, including McKesson subsidiary entities, affiliates, and registrants, (collectively, the "Released Parties") from any and all civil penalty claims under 21 U.S.C. § 842 that the United States could have asserted, or may assert in the future, against McKesson related to the Covered Conduct; and

2. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct.

C. Nothing in this Settlement Agreement shall prohibit or limit any other agency within DOJ or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any

component of DOJ, based on the Covered Conduct.

D. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the investigation and prosecution thereof by the United States.

E. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and the releases set forth herein, as to any entity or person (including McKesson) are the following:

1. Any potential criminal liability;

2. Any civil, criminal, or administrative liability arising under Title 26, United States Code (the Internal Revenue Code);

3. Any civil or administrative liability to the United States for any conduct other than the Covered Conduct, as described in paragraph III(A)-(F); and

4. Any liability based upon any obligation created by or arising under this Settlement Agreement.

F. Contemporaneously with the execution of this Settlement Agreement, McKesson will enter into the 2017 MOA, which will resolve administrative claims that DEA has or may have against McKesson related to the Covered Conduct. *See* Appendix B. McKesson acknowledges that it is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken, is taking, and will be taking further good faith actions to detect and prevent diversion. *See* Compliance Addendum attached hereto in Appendix B.

G. Nothing in this Settlement Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against McKesson for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct as described in Section III of this Settlement Agreement or which occur after the Effective Date of this Settlement Agreement.

H. McKesson agrees that any and all costs it has, will, or may incur in connection with this matter – including payment of the Settlement Amount under this Settlement Agreement, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action - shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

I. McKesson warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following its payment to the United States of the Settlement Amount. Furthermore, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to McKesson, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to

defraud any entity to which McKesson was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

J. If, within 91 days of the Effective Date of this Settlement Agreement or of any payment made hereunder, McKesson commences, or a third-party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (i) seeking to have any order for relief of McKesson's debts, or seeking to adjudicate McKesson as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for McKesson or for all or any substantial part of McKesson's assets, McKesson agrees as follows:

1. McKesson's obligations under this Settlement Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and McKesson will not argue or otherwise take the position in any such case, proceeding, or action that: (i) McKesson's obligations under this Settlement Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) McKesson was insolvent at the time this Settlement Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Settlement Agreement do not constitute a contemporaneous exchange for new value given to McKesson;

2. If McKesson's obligations under this Settlement Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Settlement Agreement, and bring any civil claims that would otherwise be covered by the release provided in Paragraph 2, above. McKesson agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that McKesson will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that McKesson will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought

by the United States within 90 calendar days of written notification to McKesson that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of the Settlement Agreement; and (iii) the United States may pursue any and all claims it had as of July 1, 2014, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

3. McKesson acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided by and through this Settlement Agreement.

K. Each Party to this Settlement Agreement will bear its own legal expenses and other costs incurred in connection with this matter, including those for the preparation and performance of this Settlement Agreement.

L. This Settlement Agreement is intended to be for the benefit of the Parties only.

M. McKesson represents that this Settlement Agreement is freely and voluntarily entered into, without any degree of duress or compulsion whatsoever. McKesson also acknowledges that it was represented by legal counsel of its choosing throughout the negotiation and execution of this Settlement Agreement.

N. McKesson consents to the disclosure of this Settlement Agreement, information about this Settlement Agreement, and the settlement memorialized herein by the United States to the public.

O. Nothing in this Settlement Agreement constitutes an agreement by the United States concerning characterization of the Settlement Amount for purposes of Title 26 of the United States Code (Internal Revenue Code).

VI. GENERAL PROVISIONS

A. Governing Law: This Settlement Agreement is governed by the laws of the United States of America. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties regarding this Settlement Agreement and its terms shall be the United States District Court for the Northern District of West Virginia.

B. Headings: The section and paragraph headings in this Settlement Agreement are inserted solely for the convenience of the Parties and shall not be construed to be part of or in any way affect the substantive provisions of this Settlement Agreement.

C. Merger Clause: This Settlement Agreement, including Attachments, constitutes the complete agreement and understanding by and between the United States and McKesson with respect to the settlement of claims against McKesson arising out of the Covered Conduct and no promises, agreements, or understandings, written or oral, not contained herein shall be of any force or effect. This Settlement Agreement may be amended at any time by mutual consent of the parties hereto, with any such amendment to be invalid, unless in writing, signed by an authorized agent of McKesson and an authorized representative of the United States.

D. Counterparts: This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

E. Binding: This Settlement Agreement is binding on McKesson and its successors, transferees, and assigns.

F. Effective Date: This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.

G. Drafting: For purposes of construing this Settlement Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

H. Authority to Sign: Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

IN WITNESS WHEREOF, the United States and McKesson have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

THE UNITED STATES OF AMERICA

Dated: 12/30/2016

William J. Ihlenfeld, II
U.S. Attorney
Northern District of West Virginia

Dated: 1/17/17

Robert C. Troyer
Acting U.S. Attorney
District of Colorado

THE UNITED STATES OF AMERICA

Dated: 2/3/17

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: 1/3/2017

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: 01-05-17

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: 1-6-17

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: 1/4/17

Deborah R. Gilg
U.S. Attorney
District of Nebraska

Dated: _____

Phillip A. Talbert
U.S. Attorney
Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: _____

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

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Eastern District of California

Dated: 1/6/17

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Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: 1/4/17

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: 1-3-17

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: 1/5/17

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

A. Lee Bentley, III
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Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: 1/5/17

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

McKESSON CORPORATION

Dated: 1/5/17

Lori A. Scheckter
Executive Vice President, General Counsel and
Chief Compliance Officer for
McKesson Corporation

Dated: 1/5/17

Geoffrey E. Hobart
Covington & Burling LLP
Counsel for McKesson Corporation

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at [redacted]9th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425.

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RM0173055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration RM0220537, located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at 7009 South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at 10504 McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration PM0021535, located at 3775 Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f. The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1. Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number [redacted]

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number PM0030849. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration RM0220688, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration [redacted] for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, *e.g.*, administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration [redacted], and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration [redacted], to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or

e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, [redacted] Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, [redacted] Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, [redacted] (2 Constitution Square) [redacted] East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post Street, [redacted]
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
[redacted] State Highway [redacted]
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post Street [redacted]
San Francisco, CA 94104

7. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8. Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

By Louis Milione for

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

CERTIFICATE OF SERVICE

I hereby certify that on the 9 day of April, 2018, a true and correct copy of the foregoing STIPULATION AND ORDER has been served on the parties of record in this proceeding by mailing a copy thereof, properly addressed by first class mail with postage prepaid, to the following:

MCKESSON CORPORATION
DBA MCKESSON DRUG COMPANY
[redacted]KERSKILL AVENUE
WASHINGTON COURT HOUSE OH 43160

and caused a copy to be electronically mailed to:

L. Mitchell Jones, Assistant Attorney General
[redacted]

Carol Inglesby
Administrative Assistant
Division of Occupational
and Professional
Licensing

L. MITCHELL JONES (U.S.B. 5979)
Assistant Attorney General
SEAN D. REYES (U.S.B. 7969)
Utah Attorney General
Commercial Enforcement Division
Heber M. Wells Building
Box 140872
Salt Lake City, UT 84114-6741
Telephone: (801) 366-0310

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSE OF **MCKESSON CORPORATION** UTAH LICENSE #9094482-8913 TO DISPENSE CONTROLLED SUBSTANCES IN THE STATE OF UTAH	)))))	STIPULATION AND ORDER CASE NO. [redacted]

MCKESSON CORPORATION ("Respondent") and the **DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING** of the Department of Commerce of the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action. Ammie McAsey is authorized to sign this Stipulation on behalf of Respondent.

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to a hearing, the right to call witnesses on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to all administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-4-901 through R151-4-907. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation and Order, and will release other information about this disciplinary action against Respondent's license, to other persons and entities.

7. Respondent admits the following facts are true:

a. Respondent was first licensed to dispense controlled substances in the State of Utah on July 23, 2014. Respondent is based in Aurora, Colorado.

b. On or about January 5, 2017, Respondent entered into a "Settlement Agreement and Release" with the U.S. Department of Justice on behalf of the Drug Enforcement Administration, a copy of which is incorporated by reference to this Stipulation and Order and attached as Exhibit A.

c. On or about January 5, 2017, Respondent entered into an "Administrative Memorandum of Agreement" with the U.S. Department of Justice, Drug Enforcement Administration ("DEA"), a copy of which is incorporated by reference to this Stipulation and Order and attached as Exhibit B.

d. Pursuant to the Settlement Agreement and Release and the Administrative Memorandum and Agreement, Respondent agreed to the suspension of Respondent's DEA registration from January 17, 2017 to January 17, 2020.

e. The suspension of the DEA registration described in Exhibits A and B would constitute misconduct in the State of Utah.

f. Utah Code Ann. § 58-37-6(4)(g) provides that when an individual's DEA registration is suspended, then the Division shall immediately suspend the individual's Utah controlled substance license.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(d); and that said conduct justifies disciplinary action against Respondent's license pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent agrees that an Order, which constitutes disciplinary action against Respondent's licenses by the Division pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2), shall be entered in this matter as follows:

(a) Respondent's Utah license to distribute controlled substances shall be immediately suspended and remain suspended until January 17, 2020, or until DEA lifts the suspension and re-instates the registration.

(b) The suspension shall not apply to, or limit, Respondent's right to distribute, or engage in operations, involving List I chemical products, at or from Respondent, which are permitted under the Settlement Agreement and Release

and Administrative Memorandum of Agreement.

(c) The Division's action in this Stipulation and Order does not affect any legal ability or inability of Respondent to possess and distribute controlled substances to federal customers under Respondent's exclusive contract with the U.S. Department of Veterans Affairs.

9. Upon approval by the Director of the Division this Stipulation and Order shall be the final compromise and settlement of this non-criminal administrative matter. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of her having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this

Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may subject Respondent to revocation or other sanctions.

13. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

14. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

15. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

BY: _____
JENNIFER ZAELIT
Bureau Manager

DATE: 4/5/2018

RESPONDENT

BY: _____
AMMIE McASEY

DATE: April 4, 2018

SEAN D. REYES
UTAH ATTORNEY GENERAL

BY: _____
L. MITCHELL JONES
Counsel for the Division

DATE: 5 Apr 18

ORDER

THE ABOVE STIPULATION, in the matter of **MCKESSON CORPORATION,** is hereby approved by the Division of Occupational and Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

DATED this 9 day of April, 2018.

DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

MARK B. STEINAGEL
Director

Investigator: Sharilee McIntyre

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release ("Settlement Agreement" or "Agreement") is entered into between the United States of America, acting through the United States Department of Justice ("DOJ"),[1] and on behalf of the Drug Enforcement Administration ("DEA") (collectively referred to herein as the "United States"), and McKesson Corporation ("McKesson").

II. RECITALS

A. McKesson is a corporation organized and existing under the laws of the State of Delaware. McKesson's corporate headquarters and principal place of business is located at One Post Street, San Francisco, California.

B. McKesson is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. McKesson distributes pharmaceuticals through a network of distribution centers located throughout the United States, including distribution centers located in the following areas: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; La Crosse, Wisconsin; Lakeland, Florida; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California. McKesson formerly distributed pharmaceuticals through a distribution center located in Landover, Maryland, which closed in January 2012 (the "Landover Distribution Center"), and in La Vista, Nebraska, which closed in October 2016. A list of all McKesson U.S. Pharmaceutical distribution

[1] The Department of Justice is represented by the following 12 U.S. Attorney's Offices: Central District of California; Eastern District of California; District of Colorado; Middle District of Florida; Eastern District of Kentucky; Northern District of Illinois; District of Massachusetts; Eastern District of Michigan; District of Nebraska; District of New Jersey; Northern District of West Virginia; and Western District of Wisconsin.

Ex A

centers that hold a DEA Certificate of Registration as of the Effective Date of this Agreement is attached hereto as Appendix A. Collectively, the distribution centers listed in Appendix A and the Landover Distribution Center are referred to herein as the "McKesson Distribution Centers."

C. At times relevant to this Agreement, the McKesson Distribution Centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* (the "CSA" or the "Act"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

D. The DEA is the DOJ component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

E. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

F. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. § 1301.74(b).

G. The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. § 1301.74(b). *See* 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

III. COVERED CONDUCT

The United States contends that it has certain civil claims against McKesson under 21 U.S.C. §§ 821, 823, 827, and 842(a)(5) for engaging in the following conduct (the "Covered Conduct") from January 1, 2009, through the Effective Date as that term is defined in Section

VI(F) (the "Covered Time Period"):

A. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations at McKesson Distribution Centers, including the following specific centers:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
La Crosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;
Washington Courthouse, Ohio; and
West Sacramento, California.

B. In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to herein as the "2008 Agreements") arising out of, among other things, McKesson's failure to report suspicious orders of controlled substances to the DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP") in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to the DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b).

C. McKesson failed to follow the procedures and policies set forth in the McKesson

CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP.

D. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers during the Covered Time Period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements.

E. McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined by the DEA in three letters from the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including McKesson, on September 27, 2006, February 7, 2007, and December 27, 2007.

F. Certain McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

IV. ACCEPTANCE OF RESPONSIBILITY

A. On or about September 27, 2006, February 7, 2007, and December 27, 2007, DEA's

Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum. The Compliance Addendum is an attachment to the Administrative Memorandum of Agreement (the "2017 MOA") entered into by McKesson and DEA contemporaneously with this Agreement. The Compliance Addendum and the 2017 MOA are attached hereto as Appendix B.

B. On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided, among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its CSMP. McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to

prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

V. TERMS AND CONDITIONS

In consideration of the mutual promises, covenants, and obligations set forth in this Settlement Agreement, the United States and McKesson agree as follows:

A. McKesson shall pay the United States the sum of One Hundred Fifty Million Dollars ($150,000,000.00) (the "Settlement Amount") within five (5) business days of the Effective Date of this Settlement Agreement, by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the United States.

B. In consideration of the fulfillment of the payment of the Settlement Amount, the United States agrees to:

1. Fully and finally release McKesson and all McKesson facilities, including McKesson subsidiary entities, affiliates, and registrants, (collectively, the "Released Parties") from any and all civil penalty claims under 21 U.S.C. § 842 that the United States could have asserted, or may assert in the future, against McKesson related to the Covered Conduct; and

2. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct.

C. Nothing in this Settlement Agreement shall prohibit or limit any other agency within DOJ or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any

component of DOJ, based on the Covered Conduct.

D. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the investigation and prosecution thereof by the United States.

E. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and the releases set forth herein, as to any entity or person (including McKesson) are the following:

1. Any potential criminal liability;

2. Any civil, criminal, or administrative liability arising under Title 26, United States Code (the Internal Revenue Code);

3. Any civil or administrative liability to the United States for any conduct other than the Covered Conduct, as described in paragraph III(A)-(F); and

4. Any liability based upon any obligation created by or arising under this Settlement Agreement.

F. Contemporaneously with the execution of this Settlement Agreement, McKesson will enter into the 2017 MOA, which will resolve administrative claims that DEA has or may have against McKesson related to the Covered Conduct. *See* Appendix B. McKesson acknowledges that it is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken, is taking, and will be taking further good faith actions to detect and prevent diversion. *See* Compliance Addendum attached hereto in Appendix B.

G. Nothing in this Settlement Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against McKesson for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct as described in Section III of this Settlement Agreement or which occur after the Effective Date of this Settlement Agreement.

H. McKesson agrees that any and all costs it has, will, or may incur in connection with this matter – including payment of the Settlement Amount under this Settlement Agreement, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action - shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

I. McKesson warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following its payment to the United States of the Settlement Amount. Furthermore, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to McKesson, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to

defraud any entity to which McKesson was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

J. If, within 91 days of the Effective Date of this Settlement Agreement or of any payment made hereunder, McKesson commences, or a third-party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (i) seeking to have any order for relief of McKesson's debts, or seeking to adjudicate McKesson as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for McKesson or for all or any substantial part of McKesson's assets, McKesson agrees as follows:

> 1. McKesson's obligations under this Settlement Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and McKesson will not argue or otherwise take the position in any such case, proceeding, or action that: (i) McKesson's obligations under this Settlement Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) McKesson was insolvent at the time this Settlement Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Settlement Agreement do not constitute a contemporaneous exchange for new value given to McKesson;
>
> 2. If McKesson's obligations under this Settlement Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Settlement Agreement, and bring any civil claims that would otherwise be covered by the release provided in Paragraph 2, above. McKesson agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that McKesson will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that McKesson will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought

by the United States within 90 calendar days of written notification to McKesson that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of the Settlement Agreement; and (iii) the United States may pursue any and all claims it had as of July 1, 2014, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

3. McKesson acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided by and through this Settlement Agreement. .

K. Each Party to this Settlement Agreement will bear its own legal expenses and other costs incurred in connection with this matter, including those for the preparation and performance of this Settlement Agreement.

L. This Settlement Agreement is intended to be for the benefit of the Parties only.

M. McKesson represents that this Settlement Agreement is freely and voluntarily entered into, without any degree of duress or compulsion whatsoever. McKesson also acknowledges that it was represented by legal counsel of its choosing throughout the negotiation and execution of this Settlement Agreement.

N. McKesson consents to the disclosure of this Settlement Agreement, information about this Settlement Agreement, and the settlement memorialized herein by the United States to the public.

O. Nothing in this Settlement Agreement constitutes an agreement by the United States concerning characterization of the Settlement Amount for purposes of Title 26 of the United States Code (Internal Revenue Code).

VI. GENERAL PROVISIONS

A. Governing Law: This Settlement Agreement is governed by the laws of the United States of America. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties regarding this Settlement Agreement and its terms shall be the United States District Court for the Northern District of West Virginia.

B. Headings: The section and paragraph headings in this Settlement Agreement are inserted solely for the convenience of the Parties and shall not be construed to be part of or in any way affect the substantive provisions of this Settlement Agreement.

C. Merger Clause: This Settlement Agreement, including Attachments, constitutes the complete agreement and understanding by and between the United States and McKesson with respect to the settlement of claims against McKesson arising out of the Covered Conduct and no promises, agreements, or understandings, written or oral, not contained herein shall be of any force or effect. This Settlement Agreement may be amended at any time by mutual consent of the parties hereto, with any such amendment to be invalid, unless in writing, signed by an authorized agent of McKesson and an authorized representative of the United States.

D. Counterparts: This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

E. Binding: This Settlement Agreement is binding on McKesson and its successors, transferees, and assigns.

F. Effective Date: This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.

G. Drafting: For purposes of construing this Settlement Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

H. Authority to Sign: Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

IN WITNESS WHEREOF, the United States and McKesson have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

THE UNITED STATES OF AMERICA

Dated: 12/30/2016

William J. Ihlenfeld, II
U.S. Attorney
Northern District of West Virginia

Dated: 1/17/17

Robert C. Troyer
Acting U.S. Attorney
District of Colorado

THE UNITED STATES OF AMERICA

Dated: 2/2-/17

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: 1/3/2017

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: 01-05-17

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: 1-6-17

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: 1/4/17

Deborah R. Gilg
U.S. Attorney
District of Nebraska

Dated: _____

Phillip A. Talbert
U.S. Attorney
Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: _____

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: _____

Deborah R. Gilg
U.S. Attorney
District of Nebraska

Dated: 1/4/17

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Dated: _____

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Dated: _____

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District of New Jersey

THE UNITED STATES OF AMERICA

Dated: _____

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U.S. Attorney
District of Nebraska

Dated: _____

Phillip A. Talbert
U.S. Attorney
Eastern District of California

Dated: 1/6/17

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U.S. Attorney
District of Massachusetts

Dated: _____

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U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: _____

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District of Nebraska

Dated: _____

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U.S. Attorney
Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: 1/4/17

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: 1-3-17

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

_____
A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: 1/5/17

_____
Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

_____
Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: 1/5/17

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

McKESSON CORPORATION

Dated: 1/5/17

Lori A. Schechter
Executive Vice President, General Counsel and
Chief Compliance Officer for
McKesson Corporation

Dated: 1/5/17

Geoffrey E. Hobart
Covington & Burling LLP
Counsel for McKesson Corporation

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425.

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RM0173055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration [redacted], located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration [redacted], located at [redacted] 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at [redacted] McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration [redacted] located at [redacted] Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f. The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1 Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number PM0018425.

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number [redacted] McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration [redacted] for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number [redacted] McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration [redacted] for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration [redacted] for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, *e.g.*, administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration [redacted], to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or

e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, [redacted] Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, [redacted] Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, [redacted] (2 Constitution Square), 2nd Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post Street [redacted]
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
[redacted] Highway [redacted]
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post Street, [redacted]
San Francisco, CA 94104

7. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8. Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9 Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

By J. Louis Milione for

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

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January 17, 2017

VIA E-MAIL - [redacted]
and CERTIFIED MAIL

Mr. Dane Ishihara
Bureau Manager
Division of Occupational and Professional Licensing
Herber M. Wells building, [redacted] Lobby
[redacted]00 S
Salt Lake City, UT 84111

Dear Mr. Ishihara:

McKesson Corporation, the Drug Enforcement Administration (DEA) and the Department of Justice (DOJ) have finalized the settlement agreement previously announced in 2015 to resolve allegations that starting in January 2009 certain McKesson US Pharmaceutical distribution centers failed to report suspicious orders of controlled substances to the DEA. This notice is delivered to you pursuant to our wholesaler licensure notification requirements as well as Utah Code Ann. § 58-17b-502(12).

Under the terms of the settlement agreement, McKesson has agreed to make a settlement payment to the DOJ pursuant to 21 U.S.C. § 842(c) and the DEA will temporarily suspend the DEA registrations of the following distribution centers on a staggered basis with a wholesale license and controlled substances registration in your state:

1. Aurora, Colorado (9094482-1710, 9094482-8913) - three year suspension, effective from 1/17/17 to 1/17/20; and
2. Washington Court House, Ohio (9094524-1710, 9094524-8913) - two year suspension, effective from 1/18/19 to 1/18/21;

Please note that McKesson has received a partial exception to the suspension for the Washington Court House, Ohio location, which is still permitted, at its option, to possess and distribute controlled substances related to servicing federal customers that purchase from McKesson under an exclusive contract with the United States Department of Veterans Affairs (VA). In order for

the DEA carve-out to be effective, it is essential that these locations are able to possess and distribute controlled substances for this purpose under the same time frame in your state as well.

The following facilities hold a wholesale registration and controlled substances license in Utah and are listed in the settlement agreement as facilities whose records were reviewed, however the DEA took no action against these facilities:

- Santa Fe Springs, California (5371742-1710, 5371742-8913)
- W. Sacramento, California (9094518-1710, 9094518-8913)
- Aurora, Illinois (9094475-1710, 9094475-8913)

McKesson US Pharmaceutical is extremely proud of its industry-leading controlled substances monitoring program and the enhancements it has made to date. We look forward to continuing to work collaboratively in an effort to address the substance abuse epidemic currently facing our country.

If you have any questions about this notice, please contact me at [redacted] or [redacted]

Sincerely,

Roger Morris, R.Ph., J.D.
Counsel for McKesson Corporation

CERTIFICATE OF SERVICE

I hereby certify that on the 9 day of April, 2018, a true and correct copy of the foregoing STIPULATION AND ORDER has been served on the parties of record in this proceeding by mailing a copy thereof, properly addressed by first class mail with postage prepaid, to the following:

MCKESSON CORPORATION
[redacted] AVENUE
AURORA CO 80011

and caused a copy to be electronically mailed to:

L. Mitchell Jones, Assistant Attorney General
[redacted]

Carol Inglesby
Administrative Assistant
Division of Occupational
and Professional
Licensing

Oregon
Kate Brown, Governor

Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: (971) 673-0001
Fax: (971) 673-0002
Pharmacy.board@oregon.gov
www.oregon.gov/pharmacy

February 17, 2021

MCKESSON DRUG CO
3000 KENSKILL AVE
WASHINGTON CT HOUSE OH 43160

Re: [redacted]

This letter will confirm the end of your license suspension for license number [redacted] as of 2/16/2021.

If you have any questions, or need further assistance, please contact me our office at [redacted] Please provide your name, your preferred contact information, case number as it appears above, and your concerns.

Sincerely,

Kim Oster
Compliance Coordinator

CC: Oregon Board of Pharmacy Licensing Department
National Practitioner Data Bank

RECEIVED
MAY 30 2018

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of	)	Case No. [redacted]
MCKESSON DRUG COMPANY dba: MCKESSON DRUG CO	)	CONSENT ORDER
Registrant	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Disciplinary Action; Answer Required ("Notice"), hereby incorporated by reference, regarding the registrant in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the registrant as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the registrant is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the registrant neither admits nor denies the facts alleged in the above-noted Notice are true, that the registrant's conduct violated the statutes and rules cited in the Notice, and that legal cause exists pursuant to ORS 689.405 for disciplinary action by the Board; and

WHEREAS, registrant acknowledges that the allegations in the Notice, if proven in a contested case proceeding would constitute grounds for disciplinary action by the Board; and

WHEREAS, the registrant consents to the disciplinary action as set forth herein;

The Board finds that the allegations in the Notice are true and hereby imposes the following sanctions:

1. The registrant's right to distribute controlled substances is suspended effective January 18, 2019 until January 18, 2021, in the same manner of their suspension with the Idaho Board of Pharmacy, effective January 18, 2019 to January 18, 2021, or for such other dates as the DEA implements in its suspension with the following conditions:

   a. Registrant shall notify the Board if the DEA or Idaho suspension dates are changed.
   b. The suspension will not apply to or limit Registrant's authority to distribute, or operations involving, List I Chemical Products at or from Registrant that are authorized under Registrant's DEA registration and the DEA Settlement Agreement. Registrant is permitted, at its option, to possess and distribute

controlled substances to federal customers that purchase controlled substances from Registrant under an exclusive contract with the Veteran's Administration.

c. The registrant shall comply with all terms and conditions of the Idaho Board of Pharmacy Amended Order Restricting Controlled Substance Registration in Case No. BOP 17-054;

d. Registrant shall notify the Oregon Board in writing within 15 calendar days of any action related to their Idaho Order. Registrant shall submit said written acknowledgement to the Board office by certified mail (or other method approved by the Board in writing) within 15 calendar days and retain receipt of verification of delivery to the Board office; and

e. The registrant shall comply with all Oregon laws and rules.

2. Failure of the registrant to comply with all the requirements of this Consent Order constitutes unprofessional conduct and is grounds for revocation or any other form of discipline or sanction authorized by law.

CONSENT

I hereby acknowledge that I am the authorized representative of registrant. On behalf of the registrant, I hereby acknowledge that I have read and understand the above-noted Notice and the terms of the Consent Order. I hereby acknowledge that I understand that the Consent Order with incorporated Notice is a public record and shall be available via the Board's online licensure verification; is available upon written request pursuant to public disclosure laws; and shall be reported to the National Practitioner Data Bank as required by federal law. I agree to the Board entering the Consent Order.

Dennis McKsey — 5-29-2018

Authorized Representative — Date

MCKESSON DRUG COMPANY dba:
McKesson Drug Co
Registrant (Registration No. W1-0001872-CS)

IT IS SO ORDERED.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

[signature] — 5/31/18

Brianne Efremoff, Pharm.D. R.Ph.. — Date
Compliance Director

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of	)	Case No. [redacted]
MCKESSON DRUG COMPANY dba: MCKESSON DRUG CO	)	NOTICE OF PROPOSED DISCIPLINARY ACTION; ANSWER REQUIRED
Registrant	)	

Under the authority granted pursuant to ORS 689.135, 689.145, 689.335, 689.405 and 689.445, the Oregon Board of Pharmacy proposes to take disciplinary action against your Certificate of Registration No. [redacted] because McKesson Drug Co violated the Oregon Pharmacy Act and the Board of Pharmacy rules as set forth below:

McKesson failed to maintain effective controls against diversion and did not identify or report to DEA suspicious orders from on or about 1/1/2009 to 1/17/2017.

On 1/17/2017, McKesson entered into an Administrative Memorandum of Agreement with the United States Department of Justice and the Drug Enforcement Agency, hereby incorporated by reference. Information in the Agreement includes grounds for disciplinary action by the Board.

On 6/29/2017, the Idaho Board of Pharmacy issued an Amended Order Restricting Controlled Substance Registration in Case No. BOP 17-054 based on the agreement with the DEA.

The above conduct is in violation of, and grounds for discipline pursuant to 21 USC 823(b)(1), 21 USC 842(a)(5), 21 CFR 1301.74(b), ORS 689.405(1)(e)(B) and (j), OAR 855-065-007(3), and OAR 855-065-0010(1) and (6)(k).

Based on these alleged violations, the Board proposes to revoke your registration and impose a $10,000 civil penalty per violation.

HEARING RIGHTS

The corporation is entitled to a hearing as provided by the Administrative Procedures Act (ORS chapter 183). An attorney must represent the corporation. If the corporation wishes to have a hearing, the corporation's attorney must file a written request for hearing with the Board within 21 days from the date this notice was mailed. The corporation's attorney may send or deliver a request for hearing to:

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150

Portland, OR 97232
Fax: (971) 673-0002

If a request for hearing is not received within this 21-day period, the corporation's right to a hearing shall be considered waived.

If the corporation requests a hearing, the corporation's attorney will be notified of the time and place of the hearing. Before the commencement of the hearing, the corporation will be given information on the procedures, right of representation and other rights of parties relating to the conduct of the hearing.

If the corporation does not request a hearing within 21 days, or if it withdraws a hearing request, notifies the Board or Administrative Law Judge that it will not appear, or fails to appear at a scheduled hearing, the Board may issue a final order by default imposing discipline. If the Board issues a final order by default, it designates its file on this matter as the record.

ANSWER REQUIRED

Pursuant to OAR 855-001-0010 and OAR 855-001-0015, if you request a hearing you must also provide, within 21 days from the date this contested case notice was served, a written answer to the allegations set forth in this contested case notice. Your written answer must include an admission or denial of each factual matter alleged in the notice and a short and plain statement of each relevant affirmative defense you may have. Except for good cause, factual matters alleged in the notice and not denied in the answer shall be presumed admitted; failure to raise a particular defense in the answer will be considered a waiver of such defense; new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and evidence shall not be taken on any issue not raised in the notice and the answer.

Hearing Request and Answers:
Consequences of Failure to Answer
855-001-0015

(1) A hearing request, and answer when required, shall be made in writing to the Board by the party or his attorney and an answer shall include the following:

(a) An admission or denial of each factual matter alleged in the notice;

(b) A short and plain statement of each relevant affirmative defense the party may have.

(2) Except for good cause:

(a) Factual matters alleged in the notice and not denied in the answer shall be presumed admitted;

(b) Failure to raise a particular defense in the answer will be considered a waiver of such defense;

(c) New matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and

(d) Evidence shall not be taken on any issue not raised in the notice and the answer.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Brianne Efremoff, Pharm.D, R.Ph.,
Compliance Director

10/31/17
Date

DATE OF MAILING 11/1/2017

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: **MCKESSON DRUG COMPANY**
Permit Number: [redacted]
Case Number: [redacted]

CONSENT ORDER

JURISDICTION AND PROCEDURAL HISTORY

The Virginia Board of Pharmacy ("Board") and Scott Miller, authorized representative, McKesson Drug Company, as evidenced by their signatures hereto, in lieu of proceeding to an informal conference, enter into the following Consent Order affecting McKesson Drug Company's permit to operate as a non-resident wholesale distributor in the Commonwealth of Virginia.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On January 19, 2000, the Board issued Permit Number [redacted] to McKesson Drug Company ("McKesson") to operate as a non-resident wholesale distributor in the Commonwealth of Virginia. Said permit is scheduled to expire on February 28, 2019. At all times relevant hereto, said permit was in full force and effect.

2. McKesson violated Virginia Code § 54.1-3316(8) in that on January 17, 2017, by settlement with the United States Drug Enforcement Administration ("DEA"), McKesson's authority to distribute controlled substances from its Livonia, Michigan, distribution center, DEA Certificate of Registration [redacted], was suspended for a period of two years. Not included in this suspension was McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia, Michigan, distribution center, which are authorized under DEA registration number [redacted] Also not included in this suspension was McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances

from McKesson's Livonia, Michigan distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

3. McKesson violated Virginia Code § 54.1-3316(10) in that on October 17, 2017, by Consent Agreement, the Louisiana Board of Pharmacy suspended McKesson's Louisiana Controlled Dangerous Substance License for McKesson's Livonia, Michigan, distribution center from June 29, 2017 to January 17, 2019. Additionally, on March 14, 2018, by Consent Agreement, the Iowa Board of Pharmacy suspended McKesson's Controlled Substances Act Registration for McKesson's Livonia, Michigan, distribution center from March 14, 2018 to January 17, 2019. Actions by the Louisiana Board of Pharmacy and the Iowa Board of Pharmacy did not include the suspension of McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia, Michigan distribution center, which are authorized under DEA registration number [redacted] These Actions also did not affect McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson's Livonia, Michigan distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

CONSENT

McKesson Drug Company, by affixing the signature of a representative hereon to this Order, agrees to the following:

1. McKesson has been advised to seek advice of counsel prior to signing this document and is represented by Roger Morris, Esq.;

2. McKesson is fully aware that without its consent, no legal action can be taken against it or its permit except pursuant to the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*;

3. McKesson acknowledges that it has the following rights, among others: the right to an informal fact-finding conference before the Board; and the right to representation by counsel;

4. McKesson waives its right to an informal conference;

5. McKesson admits to the Findings of Fact and Conclusions of Law contained herein and waives its right to contest such Findings of Fact and Conclusions of Law and any sanction imposed hereunder in any future judicial or administrative proceeding in which the Board is a party;

6. McKesson consents to the entry of the following Order affecting its right to operate as a non-resident wholesale distributor in the Commonwealth of Virginia.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS as follows:

1. McKesson Drug Company shall not distribute Schedule II-V controlled substances from its Livonia, Michigan, distribution center into the Commonwealth of Virginia from the date of entry of this Order until January 17, 2019. This restriction shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia, Michigan, distribution center, which are authorized under the DEA registration number [redacted]. This restriction also shall not apply to or limit McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson's Livonia, Michigan distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

2. McKesson Drug Company shall comply with all laws and regulations governing the practice of a non-resident wholesale distributor in the Commonwealth of Virginia.

3. Any violation of the foregoing terms and conditions of this Order or any statute or regulation governing the practice of a non-resident wholesale distributor shall constitute grounds for further disciplinary action.

Pursuant to Virginia Code §§ 2.2-4023 and 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran, RPh, DPh
Executive Director
Virginia Board of Pharmacy

ENTERED: 12/17/18

SEEN AND AGREED TO:

Ammie McAsey
~~Scott Miller~~, representative for Ammie McAsey
McKesson Drug Company

COMMONWEALTH OF VIRGINIA STATE OF TEXAS
COUNTY/CITY OF DALLAS, TO WIT:

Subscribed and sworn to before me, a notary public in and for the Commonwealth of Virginia at large, on this 30TH day of NOVEMBER, 2018.

NICOLE VALLEY
Notary Public, State of Texas
My Commission Expires
September 29, 2019

Nicole Valley
Notary Public

My commission expires: SEPTEMBER 29, 2019

Registration No.: 13038666-0

CERTIFIED TRUE COPY
BY:
VIRGINIA BOARD OF PHARMACY

STATE OF CONNECTICUT

BEFORE THE COMMISSIONER OF CONSUMER PROTECTION

In the Matter of

McKesson Corporation

Case Nos. [redacted]

Settlement Agreement Concerning

Wholesaler / Distributor of Drugs License of McKesson Corporation

This Settlement Agreement Concerning Wholesaler / Distributor of Drugs License of McKesson Corporation ("Settlement Agreement") is entered into by the duly authorized representative for McKesson Corporation ("Licensee") and the Commissioner of the Department of Consumer Protection ("Commissioner") in accordance with Sections 4-177(c), 21a-8 and 21a-70 of the Connecticut General Statutes.

PARAGRAPH ONE: Licensee is the holder of Connecticut Wholesaler / Distributor of Drugs License No. CSW 369 for a distribution center located at 280 Dividend Road, Rocky Hill, Connecticut.

PARAGRAPH TWO: The Department of Consumer Protection's Drug Control Division ("Department") has conducted an investigation and alleges the following violations committed from in or around May 2016 to January 2018:

1. Licensee is subject to an enforcement action, in particular suspension, revocation, probation or refusal to renew their registration for a violation of provisions of federal or state statutes or regulations concerning drugs in accordance with Section 21a-70(d)(5) of the Connecticut General Statutes;
2. Licensee, through its contracted carrier, failed to operate in compliance with applicable federal state and local statutes, regulations and ordinances, including any applicable laws concerning controlled substances, drug product salvaging or reprocessing in violation of Section 21a-70(e) of the Connecticut General Statutes;

3. Licensee, through its contracted carrier, failed to provide adequate control against the diversion, theft, and loss of drugs in violation of Section 21a-70(d)(4) of the Connecticut General Statutes and Sections 21a-262-4(c) and 21a-262-2(b) of the Regulations of Connecticut State Agencies; and
4. Licensee, through its contracted carrier, failed to maintain all equipment used for storage of controlled substances securely locked except for the actual time required to remove or replace needed items in violation of Sections 21a-262-4(c) and 21a-262-2(c) of the Regulations of Connecticut State Agencies.

PARAGRAPH THREE: In lieu of a hearing and without making any admission of guilt, Licensee has:

1. Provided the Department with its policies and procedures for training their delivery drivers and securing their delivery vehicles and the drugs contained therein; and
2. Participated in a Department training on May 9, 2018 regarding policies and procedures, best practices and Connecticut laws for Licensee's delivery drivers and securing delivery vehicles and the drugs contained therein.

PARAGRAPH FOUR: In lieu of a hearing and without making any admission of guilt, Licensee agrees to:

1. Maintain all records generated pursuant to the terms of this Settlement Agreement and have said records readily available for inspection by the Department, understanding that due to the closure of Licensee's distribution center in September 2018 that all records have been transferred to a New York distribution center; and

2. Pay a civil penalty of Ten Thousand Dollars ($10,000.00). This civil penalty shall be made payable to "Treasurer, State of Connecticut" and be deposited into the Consumer Protection Enforcement Fund (Account #35125) in accordance with Connecticut General Statutes, Section 21a-8a.

PARAGRAPH FIVE: Licensee agrees to waive:

1. any right to seek judicial review or otherwise challenge or contest the validity of this Settlement Agreement;
2. any requirement that this Settlement Agreement contain findings of fact and conclusions of law; and
3. any right to a hearing or other procedural requirements of the Uniform Administrative Procedure Act, Connecticut General Statutes, Section 4-166 et seq.

PARAGRAPH SIX: This Settlement Agreement is a revocable offer of settlement that may be modified by mutual agreement or withdrawn by the Department at any time prior to its being executed and shall not become binding unless and until it is accepted and approved by the Commissioner of the Department.

[SIGNATURE PAGE TO FOLLOW]

[SIGNATURE PAGE FOR SETTLEMENT AGREEMENT CONCERNING

WHOLESALE / DISTRIBUTOR OF DRUGS LICENSE OF McKESSON CORPORATION

Case Nos. 2017-964; 2017-1876; 2018-143; 2018-731]

FOR THE LICENSEE

Dated: 11/8/18

By: _____

Name: David Morrissey

Title: VP & M

FOR THE DEPARTMENT OF CONSUMER PROTECTION

Dated: 12/27/2018

By: _____

Bryan Cafferelli
Staff Attorney

The above Settlement Agreement concerning Licensee is accepted and approved by _____ on this 4th day of January, ~~2018~~ 2019.

_____

Michelle Seagull
Commissioner of Consumer Protection

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST MCKESSON DRUG COMPANY, RESPONDENT.	: : : : :	FINAL DECISION AND ORDER 006083

Division of Legal Services and Compliance Case No. [redacted]

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

McKesson Drug Company
[redacted] Plymouth Road
Livonia, MI 48150

Wisconsin Pharmacy Examining Board
P.O. [redacted]
Madison, WI 53708-8366

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. [redacted]
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board ("Board"). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

1. Respondent, McKesson Drug Company, is licensed in the state of Wisconsin as a wholesale distributor of prescription drugs, having license number 2228-45, first issued on May 29, 2009, and current through May 31, 2020 (This wholesale distribution license, through its owner, McKesson Drug Company, is hereinafter referred to as "Respondent"). Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services ("Department") is 38220 Plymouth Road, Livonia, Michigan 48150.

2. At all times relevant to this proceeding, Respondent was a wholesale distributor of prescription drugs, located in Livonia, Michigan.

3. In 2008, McKesson Corporation ("McKesson") entered into a Settlement and Release Agreement and an Administrative Memorandum of Agreement with the United States Department of Justice, Drug Enforcement Administration ("DEA") ("the 2008 Agreement"). The 2008 Agreement arose out of, among other things, allegations regarding McKesson's failure to report suspicious orders of controlled substances, as required by 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As part of the 2008 Agreement, McKesson paid a $13.25 million civil penalty and created a Controlled Substance Monitoring Program ("CSMP").

4. On January 17, 2017, Respondent self-reported to the Board that McKesson entered into a Settlement Agreement and Release and an Administrative Memorandum of Agreement with the DEA ("the 2017 Agreement"), based on allegations that McKesson, including Respondent, had failed to adequately monitor and or report suspicious orders of controlled substances.

5. In the 2017 Agreement, the DEA alleged the following:

   a. McKesson failed to properly monitor its sales of controlled substances, including:

      i. failure to follow the procedures and polices set forth in the CSMP;
      ii. failure to conduct adequate due diligence of its customers;
      iii. failure to keep complete and accurate records in the CSMP files maintained for many of its customers;
      iv. bypassing suspicious order reporting procedures set forth in the CSMP; and
      v. failure to report suspicious orders—including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency.

   b. Certain McKesson distribution centers distributed controlled substances to pharmacies even though those distribution centers should have known that the pharmacists practicing at those pharmacies had failed to fulfill their corresponding responsibility to ensure that the controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes.

   c. McKesson violated the 2008 Agreement and federal law.

6. The DEA's allegations were limited to certain of McKesson's distribution centers, including Respondent.

7. The DEA's allegations were also against the following distribution centers licensed in Wisconsin: Aurora, Illinois (License No. 2230-45, Current, Active from June 3, 2009 to May 31, 2020); West Sacramento, California (License No. 1366-45, Current, Active from February 13, 2002 to May 31, 2020); LaCrosse, Wisconsin (License No. 868-45, Not Current, Active from November 12, 1996 to May 31, 2018); LaVista, Nebraska (License No. 2572-45, Not Current, Active from November 11, 2013 to May 31, 2018). The DEA took no action against these facilities and these distribution centers are not subject to this Final Decision and Order.

8. Pursuant to the 2017 Agreement, McKesson acknowledged that, at various times from January 1, 2009, through January 17, 2017, it did not identify or report to the DEA certain orders placed by certain pharmacies which McKesson should have detected as suspicious in a manner fully consistent with the requirements set forth in the 2008 Agreement.

9. The 2017 Agreement required McKesson to pay a settlement payment of $150 million and provided for a time-limited suspension of the DEA Certification of Registrations of four (4) of McKesson's distribution centers, including Respondent.

10. The suspension included an exception that permits, but does not require, Respondent, during the period of suspension, to continue to distribute controlled substances to federal customers that purchase controlled substances from Respondent under McKesson's exclusive contract with the United States Department of Veteran Affairs. The suspensions also do not apply or limit McKesson's authority to distribute, or operations involving, List 1 Chemical products from any of its distribution centers.

11. Respondent neither admits nor denies wrong-doing. In resolution of this matter, and to avoid the expense and uncertainty of litigation, Respondent consents to the entry of the following Conclusions of Law and Order.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in the Findings of Fact, Respondent, license no. [redacted], engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(17), by having been subject to disciplinary action by another licensing authority.

3. As a result of the above violations, Respondent, license no. 2228-45, is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

4. Pursuant to Wis. Stat. § 450.10(2), in addition to a limitation or suspension, the Board may, for violations of Wis. Stat. § 450.10(1), assess a forfeiture of not more than $1,000.00 for each separate offense, with each day of violation constituting a separate offense.

ORDER

1. The attached Stipulation is accepted.

2. Except as provided in paragraph 3 of this Order, the ability to distribute controlled substances under the license to practice as a wholesale distributor of prescription drugs in the state of Wisconsin issued to Respondent, license no. [redacted], is SUSPENDED for a period of two (2) years, effective from January 17, 2017, to January 17, 2019, or for the same effective dates as the suspension of the DEA Certificate of Registration for this distribution center under the 2017 Agreement. The suspension will terminate

automatically on either January 17, 2019, or upon the date the suspension of the DEA Certificate of Registration for this facility terminates. In the event that Respondent's DEA Certificate of Registration will remain suspended beyond January 17, 2019, Respondent shall notify the Board prior to January 17, 2019, of the continued suspension of its DEA Certificate of Registration and the date that the suspension of its DEA Certification of Registration will terminate.

3. This suspension shall not apply to or limit Respondent's authority to distribute, or Respondent's operations involving, List 1 chemical products at or from Respondent which are authorized under Respondent's DEA Certificate of Registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the United States Department of Veterans Affairs.

4. The license to practice as a wholesale distributor of prescription drugs in the state of Wisconsin, issued to Respondent, license no. [redacted] is further LIMITED to require Respondent to fully comply with Administrative Memorandum of Agreement and any amendments or modifications thereto, entered into by Respondent and the United States Department of Justice, Drug Enforcement Administration and effective on January 17, 2017.

5. Within one-hundred and twenty (120) days from the date of this Order, Respondent, license no. [redacted] shall pay a FORFEITURE in the amount of fifty thousand dollars ($50,000.00).

6. Within one-hundred and twenty (120) days from the date of this Order, Respondent, license no. [redacted] shall pay costs in the amount of $1,959.00.

7. Any payments, requests, petitions, reports, and other information required by this Order may be mailed, faxed, or emailed to:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box [redacted] Madison, WI 53707-7190
Telephone [redacted]

You may also submit this information online via DSPS' Monitoring Case Management System, here:

https://app.wi.gov/DSPSMonitoring

8. In the event that Respondent violates any term of this Order, Respondent's license, license no. [redacted] to practice as a wholesale distributor in the state of Wisconsin may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order. The Board may, in addition

and/or in the alternative, refer any violation of this Order to the Division of Legal Services and Compliance for further investigation and action.

9. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by: _____ 2/29/2012
A Member of the Board Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
MCKESSON DRUG COMPANY, RESPONDENT.	:	STIPULATION
	:	0006083

Division of Legal Services and Compliance Case No. [redacted]

Respondent McKesson Drug Company, license no. [redacted] and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:

1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.

2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:

- the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
- the right to confront and cross-examine the witnesses against Respondent;
- the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
- the right to testify on Respondent's own behalf;
- the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
- the right to petition for rehearing; and
- all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.

3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation. Respondent is represented by Attorneys Roger N. Morris and Susan Brichler Trujillo.

4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining Board ("Board"). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent or Respondent's attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Annmie McAsey
McKesson Drug Company, Respondent
38220 Plymouth Road
Livonia, MI 48150
License no. 2228-45

1-16-2019
Date

Roger N. Morris, Attorney for Respondent
Quarles & Brady LLP
One Renaissance Square
Two North Central Avenue
Phoenix, AZ 85004

1-18-19
Date

Susan B Trujillo
Susan Brichler Trujillo, Attorney for Respondent
Quarles & Brady LLP
One Renaissance Square
Two North Central Avenue
Phoenix, AZ 85004

1/22/2019
Date

Zachary J. Peters, Attorney
Wisconsin Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190

1/23/19
Date

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF NEW MEXICO

IN THE MATTER OF:

Case No. [redacted]

McKESSON CORPORATION,
CS 19948,

Respondent.

STIPULATED AGREEMENT

The New Mexico Board of Pharmacy ("Board") received self-reports from McKesson Corporation ("Respondent") which stated that Respondent entered into a settlement agreement with the U.S. Department of Justice ("DOJ") on or about January 17, 2017 (the "Settlement Agreement"). The Settlement Agreement suspended the registration for the Respondent's Washington Court House Ohio location for two (2) years, effective from February 16, 2019 to February 16, 2021. The Respondent also self-reported disciplinary actions imposed by other state boards.

In lieu of instituting formal proceedings against Respondent, and in accordance with the New Mexico Controlled Substances Act, NMSA 1978 Sections 30-31-1 to -41, the New Mexico Uniform Licensing Act ("ULA"), NMSA 1978 Sections 61-1-1 to -34, and the New Mexico Pharmacy Act, NMSA 1978 Sections 61-11-1 to -29, the Board and the Respondent have agreed to resolve this matter as outlined in this Stipulated Agreement.

Findings of Fact

1. Respondent was issued a controlled substance registration and is authorized to distribute and operate in New Mexico under CS 19948. The Respondent's permit is active and will expire on January 31, 2020.

2. The Respondent is located in Washington Court House Ohio and distributes prescription drugs, including controlled drug substances into New Mexico.
3. On or about January 17, 2017, the Respondent entered into a Settlement Agreement with the DOJ based on the DOJ's allegations that McKesson failed to properly monitor its sales of controlled substances; failed to conduct adequate due diligence and keep accurate records of its sales; failed to maintain effective controls against diversion of particular controlled substances into channels other than legitimate medical, scientific and industrial channels; and failed to report suspicious orders of controlled substances to the U.S. Drug Enforcement Administration ("DEA").
4. Twelve (12) McKesson distribution centers were referenced in the Settlement Agreement, including the distribution center located in Washington Court House, Ohio.
5. Under the terms of the Settlement Agreement, the DEA registrations issued to the Aurora, Livonia, and Washington Court House distribution centers were suspended for certain periods of time on a staggered basis. Specifically, the DEA registration issued to the Respondent Washington Court House distribution center is suspended from February 16, 2019 to February 16, 2021, with the exceptions that the Respondent may possess and distribute controlled substances to federal customers which purchase controlled substances from the Respondent under the exclusive contract with the U.S. Department of Veteran's Affairs ("VA"). In addition, the suspension does not apply to or limit Respondent's authority to distribute or operations involving, List 1 Chemical products at or from Respondent's Washington Court House distribution center.
6. The Board was also notified that the following state boards of pharmacy took action that mirrors the restrictions imposed by the Settlement Agreement: Idaho Board of Pharmacy,

Louisiana Board of Pharmacy, New Hampshire Board of Pharmacy, Iowa Board of Pharmacy, Maryland Board of Pharmacy, Utah Board of Pharmacy, Oregon Board of Pharmacy and the Wisconsin Board of Pharmacy.

7. Respondent admits that the Board has jurisdiction over the Respondent and the subject matter herein.
8. Respondent acknowledges that if the allegations in the Findings of Fact were proven in a contested hearing, it would constitute grounds for disciplinary action, including suspension or revocation, of Respondent's controlled substance registration.
9. Respondent enters into this Agreement voluntarily and waives Respondent's right to have these matters heard in the manner described in the ULA, including the right to a full evidentiary hearing, and the right to appeal any decision of the board following such hearing.
10. Respondent also waives any and all time limitations set forth in the ULA, including all rights to have this matter heard within the time frame established in the ULA.
11. Respondent waives Respondent's right to assert a claim of bias or move to excuse any Board member based on the Board member's consideration of this agreement.
12. Upon execution of this Agreement, Respondent releases the Board from any and all claims potentially arising out of the Board's decision to take the actions described herein.
13. Respondent's waiver of these rights is made knowingly, intentionally, and voluntarily.
14. Respondent affirmatively states that Respondent has read this entire document and understands Respondent's responsibilities and duties in reference to this Agreement. Respondent agrees and stipulates to all of the terms of this agreement. Respondent knowingly, intentionally and voluntarily enters into and executes this Agreement and

affirms that no promises or representations have been made other than the terms and conditions expressly stated herein.

It is hereby **ORDERED** that:

A. The Respondent, McKesson Corporation, [redacted] shall be prohibited from distributing controlled substances into New Mexico effective from the date of this order to February 16, 2021. If the effective suspension dates in the Settlement Agreement referenced herein for the Washington Court House distribution center are changed, the Respondent shall immediately notify the Board of such change and the change will automatically be incorporated into this Stipulated Agreement without the need for further Board action or approval;

B. The above prohibition does not apply to or limit the Respondent's authority to distribute, or operations involving, List I Chemical Products at or from the Respondent that are authorized under the Respondent's DEA registration and the Settlement Agreement. The Respondent is also permitted, at its option, to possess and distribute controlled substances to federal customers that purchase controlled substances from the Respondent under an exclusive contract with the VA;

C. The Respondent shall comply with all laws and regulations governing the operation of a wholesale distributor in New Mexico, which includes federal and State laws governing the proper handling and distribution of controlled dangerous substances; and

D. Failure to abide by these terms shall be grounds for summary suspension of Respondent's controlled substance registration.

E. This agreement will be included in Respondent's licensing file and is a public record open to inspection by the public.

F. This agreement constitutes disciplinary action against the Respondent by the Board and is reportable to the Healthcare Integrity and Protection Data Bank.

G. This agreement is effective as of the date it is signed by the Board Chair or his designee.

SO ORDERED on this 10th day of ~~April~~ May, 2019.

McKesson Corporation
CS 19948

Richard Mazzoni, R.Ph. - Chairman
New Mexico Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that a copy the foregoing document sent via United States Postal Service certified, return receipt mail, on ~~April~~ May 10, 2019 to:

McKesson Corporation
c/o Roger Morris, R. Ph, J.D.
Quarles & Brady
Renaissance One
Two North Central Avenue
Phoenix, AZ85005-2391

Certified Return Receipt Mail
Article No.: 7012 0470 0001 4488 5791

KRISTINA M. BENAVIDEZ
FOR THE NEW MEXICO BOARD OF PHARMACY

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit No. [redacted]	)	CASE NO: [redacted]
	)	
and	)	
	)	
MCKESSON DRUG COMPANY	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	
	)	
and	)	
	)	
MCKESSON DRUG CO.	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	
	)	
and	)	
	)	
MCKESSON CORPORATION	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against McKesson Corporation d/b/a McKesson Drug Company, McKesson Drug Company, McKesson Drug Co. and McKesson Corporation (hereinafter referred to collectively as "McKesson") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties through counsel have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The parties stipulate that McKesson denies the allegations of the Statement. The Board finds that McKesson permit numbers 192158, 191852, and 193420 violated the applicable provisions based upon the conduct set out in each and every Count of the Statement. The charges against permit number 192010 shall be dismissed with prejudice.

2. McKesson shall pay to the Board an administrative fine in the amount of Fifteen Thousand dollars ($15,000.00) as to each applicable permit (192158, 191852 and 193420) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and McKesson shall not attempt to discharge the same in any bankruptcy proceeding.

3. That McKesson expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. McKesson further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, McKesson hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That McKesson agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That McKesson acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. McKesson acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the _____day of _____, 2018.

McKesson Corporation d/b/a McKesson Drug Company

By: _____
Its: Corporate Secretary

McKesson Drug Company

By: _____
Its: McKesson Corporate Secretary

McKesson Drug Co.

By: _____
Its: McKesson Corporate Secretary

McKesson Corporation

By: _____
Its: Corporate Secretary

_____
Roger N. Morris, Attorney for McKesson Corporation d/b/a/ McKesson Drug Company, McKesson Drug Company, McKesson Drug Co. and McKesson Corporation

DONE this the 24th day of May, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: _____
David Darby, R.Ph., President

By: _____
James S. Ward
Its Attorney

OF COUNSEL:
WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor Permit No. 192010	)	**CASE NO: [redacted]**
	)	
and	)	
	)	
MCKESSON DRUG COMPANY	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	
	)	
and	)	
	)	
MCKESSON DRUG CO.	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	
	)	
and	)	
	)	
MCKESSON CORPORATION	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: McKesson Corporation d/b/a McKesson Drug Company
[redacted] Fraser Street
Aurora, Colorado 80011

McKesson Drug Company
[redacted] Kenskill Avenue
Washington, Ohio 43160

McKesson Drug Co.
[redacted] Plymouth Road
Livonia, MI 48150

McKesson Corporation
[redacted] Kendrick Lane
Lakeland, Florida 33805

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on June 26th, 2018 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate McKesson Corporation d/b/a McKesson Drug Company, McKesson Drug Company, McKesson Drug Co., and McKesson Corporation (hereinafter referred to collectively as "McKesson") as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that McKesson has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to

be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

COUNT ONE

As to Permit No. 191258, based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars ($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures

and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

COUNT TWO

As to Permit No. [redacted] based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars ($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

COUNT THREE

As to Permit No. [redacted] based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars

($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

COUNT FOUR

As to Permit No. [redacted] based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars ($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-

examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 16 day of February, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT A

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release ("Settlement Agreement" or "Agreement") is entered into between the United States of America, acting through the United States Department of Justice ("DOJ"),[1] and on behalf of the Drug Enforcement Administration ("DEA") (collectively referred to herein as the "United States"), and McKesson Corporation ("McKesson").

II. RECITALS

A. McKesson is a corporation organized and existing under the laws of the State of Delaware. McKesson's corporate headquarters and principal place of business is located at One Post Street, San Francisco, California.

B. McKesson is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. McKesson distributes pharmaceuticals through a network of distribution centers located throughout the United States, including distribution centers located in the following areas: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; La Crosse, Wisconsin; Lakeland, Florida; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California. McKesson formerly distributed pharmaceuticals through a distribution center located in Landover, Maryland, which closed in January 2012 (the "Landover Distribution Center"), and in La Vista, Nebraska, which closed in October 2016. A list of all McKesson U.S. Pharmaceutical distribution

[1] The Department of Justice is represented by the following 12 U.S. Attorney's Offices: Central District of California; Eastern District of California; District of Colorado; Middle District of Florida; Eastern District of Kentucky; Northern District of Illinois; District of Massachusetts; Eastern District of Michigan; District of Nebraska; District of New Jersey; Northern District of West Virginia; and Western District of Wisconsin.

centers that hold a DEA Certificate of Registration as of the Effective Date of this Agreement is attached hereto as Appendix A. Collectively, the distribution centers listed in Appendix A and the Landover Distribution Center are referred to herein as the "McKesson Distribution Centers."

C. At times relevant to this Agreement, the McKesson Distribution Centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* (the "CSA" or the "Act"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

D. The DEA is the DOJ component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

E. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

F. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. § 1301.74(b).

G. The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. § 1301.74(b). *See* 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

III. COVERED CONDUCT

The United States contends that it has certain civil claims against McKesson under 21 U.S.C. §§ 821, 823, 827, and 842(a)(5) for engaging in the following conduct (the "Covered Conduct") from January 1, 2009, through the Effective Date as that term is defined in Section

VI(F) (the "Covered Time Period"):

A. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations at McKesson Distribution Centers, including the following specific centers:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
La Crosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;
Washington Courthouse, Ohio; and
West Sacramento, California.

B. In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to herein as the "2008 Agreements") arising out of, among other things, McKesson's failure to report suspicious orders of controlled substances to the DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP") in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to the DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b).

C. McKesson failed to follow the procedures and policies set forth in the McKesson

CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP.

D. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers during the Covered Time Period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements.

E. McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined by the DEA in three letters from the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including McKesson, on September 27, 2006, February 7, 2007, and December 27, 2007.

F. Certain McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

IV. ACCEPTANCE OF RESPONSIBILITY

A. On or about September 27, 2006, February 7, 2007, and December 27, 2007, DEA's

Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum. The Compliance Addendum is an attachment to the Administrative Memorandum of Agreement (the "2017 MOA") entered into by McKesson and DEA contemporaneously with this Agreement. The Compliance Addendum and the 2017 MOA are attached hereto as Appendix B.

B. On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided, among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its CSMP. McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to

prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

V. TERMS AND CONDITIONS

In consideration of the mutual promises, covenants, and obligations set forth in this Settlement Agreement, the United States and McKesson agree as follows:

A. McKesson shall pay the United States the sum of One Hundred Fifty Million Dollars ($150,000,000.00) (the "Settlement Amount") within five (5) business days of the Effective Date of this Settlement Agreement, by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the United States.

B. In consideration of the fulfillment of the payment of the Settlement Amount, the United States agrees to:

1. Fully and finally release McKesson and all McKesson facilities, including McKesson subsidiary entities, affiliates, and registrants, (collectively, the "Released Parties") from any and all civil penalty claims under 21 U.S.C. § 842 that the United States could have asserted, or may assert in the future, against McKesson related to the Covered Conduct; and

2. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct.

C. Nothing in this Settlement Agreement shall prohibit or limit any other agency within DOJ or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any

component of DOJ, based on the Covered Conduct.

D. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the investigation and prosecution thereof by the United States.

E. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and the releases set forth herein, as to any entity or person (including McKesson) are the following:

1. Any potential criminal liability;

2. Any civil, criminal, or administrative liability arising under Title 26, United States Code (the Internal Revenue Code);

3. Any civil or administrative liability to the United States for any conduct other than the Covered Conduct, as described in paragraph III(A)-(F); and

4. Any liability based upon any obligation created by or arising under this Settlement Agreement.

F. Contemporaneously with the execution of this Settlement Agreement, McKesson will enter into the 2017 MOA, which will resolve administrative claims that DEA has or may have against McKesson related to the Covered Conduct. *See* Appendix B. McKesson acknowledges that it is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken, is taking, and will be taking further good faith actions to detect and prevent diversion. *See* Compliance Addendum attached hereto in Appendix B.

G. Nothing in this Settlement Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against McKesson for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct as described in Section III of this Settlement Agreement or which occur after the Effective Date of this Settlement Agreement.

H. McKesson agrees that any and all costs it has, will, or may incur in connection with this matter – including payment of the Settlement Amount under this Settlement Agreement, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action - shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

I. McKesson warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following its payment to the United States of the Settlement Amount. Furthermore, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to McKesson, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to

defraud any entity to which McKesson was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

J. If, within 91 days of the Effective Date of this Settlement Agreement or of any payment made hereunder, McKesson commences, or a third-party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (i) seeking to have any order for relief of McKesson's debts, or seeking to adjudicate McKesson as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for McKesson or for all or any substantial part of McKesson's assets, McKesson agrees as follows:

1. McKesson's obligations under this Settlement Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and McKesson will not argue or otherwise take the position in any such case, proceeding, or action that: (i) McKesson's obligations under this Settlement Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) McKesson was insolvent at the time this Settlement Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Settlement Agreement do not constitute a contemporaneous exchange for new value given to McKesson;

2. If McKesson's obligations under this Settlement Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Settlement Agreement, and bring any civil claims that would otherwise be covered by the release provided in Paragraph 2, above. McKesson agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that McKesson will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that McKesson will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought

by the United States within 90 calendar days of written notification to McKesson that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of the Settlement Agreement; and (iii) the United States may pursue any and all claims it had as of July 1, 2014, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

3. McKesson acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided by and through this Settlement Agreement.

K. Each Party to this Settlement Agreement will bear its own legal expenses and other costs incurred in connection with this matter, including those for the preparation and performance of this Settlement Agreement.

L. This Settlement Agreement is intended to be for the benefit of the Parties only.

M. McKesson represents that this Settlement Agreement is freely and voluntarily entered into, without any degree of duress or compulsion whatsoever. McKesson also acknowledges that it was represented by legal counsel of its choosing throughout the negotiation and execution of this Settlement Agreement.

N. McKesson consents to the disclosure of this Settlement Agreement, information about this Settlement Agreement, and the settlement memorialized herein by the United States to the public.

O. Nothing in this Settlement Agreement constitutes an agreement by the United States concerning characterization of the Settlement Amount for purposes of Title 26 of the United States Code (Internal Revenue Code).

VI. GENERAL PROVISIONS

A. Governing Law: This Settlement Agreement is governed by the laws of the United States of America. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties regarding this Settlement Agreement and its terms shall be the United States District Court for the Northern District of West Virginia.

B. Headings: The section and paragraph headings in this Settlement Agreement are inserted solely for the convenience of the Parties and shall not be construed to be part of or in any way affect the substantive provisions of this Settlement Agreement.

C. Merger Clause: This Settlement Agreement, including Attachments, constitutes the complete agreement and understanding by and between the United States and McKesson with respect to the settlement of claims against McKesson arising out of the Covered Conduct and no promises, agreements, or understandings, written or oral, not contained herein shall be of any force or effect. This Settlement Agreement may be amended at any time by mutual consent of the parties hereto, with any such amendment to be invalid, unless in writing, signed by an authorized agent of McKesson and an authorized representative of the United States.

D. Counterparts: This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

E. Binding: This Settlement Agreement is binding on McKesson and its successors, transferees, and assigns.

F. Effective Date: This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.

G. Drafting: For purposes of construing this Settlement Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

H. Authority to Sign: Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

IN WITNESS WHEREOF, the United States and McKesson have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

THE UNITED STATES OF AMERICA

Dated: 12/30/2016

William J. Ihlenfeld, II
U.S. Attorney
Northern District of West Virginia

Dated: 1/17/17

Robert C. Troyer
Acting U.S. Attorney
District of Colorado

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

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_____
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Northern District of Illinois

Dated: _____

_____
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U.S. Attorney
Western District of Wisconsin

Dated: _____

_____
Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated. _____

_____
Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: 01-05-17

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

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U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: 1-6-17

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: 1/4/17

Deborah R. Gilg
U.S. Attorney
District of Nebraska

Dated: _____

Phillip A. Talbert
U.S. Attorney
Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: _____

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: _____

Deborah R. Gilg
U.S. Attorney
District of Nebraska

Dated: 1/9/17

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Eastern District of California

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Dated: 1/6/17

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THE UNITED STATES OF AMERICA

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U.S. Attorney
Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: 1/4/17

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: 1-5-17

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

_____
A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: 1/5/17

_____
Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

_____
Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

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A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: 1/5/17

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

McKESSON CORPORATION

Dated: 1/5/17

Lori A. Schechter
Executive Vice President, General Counsel and
Chief Compliance Officer for
McKesson Corporation

Dated: 1/5/17

Geoffrey E. Hobart
Covington & Burling LLP
Counsel for McKesson Corporation

EXHIBIT B

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at [redacted] East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration [redacted]

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration [redacted], located at 3000 Kenskill Avenue, Washington Court House, Ohio [redacted] McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration [redacted] located at [redacted] Plymouth Road, Livonia, Michigan [redacted] McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"). DEA Certificate of Registration [redacted] located at [redacted] Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration [redacted] located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration [redacted] located at [redacted] McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration [redacted] located at [redacted] Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration [redacted] located at [redacted] Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at [redacted] South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at [redacted] McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration [redacted] located at [redacted] Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2 Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland,
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4 Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5 Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II Terms and Conditions

1 Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration RM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number [redacted]

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number [redacted] McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number [redacted] McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II I e-g

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration [redacted] for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration [redacted], for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, e.g., administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration [redacted], and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration [redacted] to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or

e. Any liability based upon any obligation created by or arising under this Agreement

III. Miscellaneous

1 Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2 Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3 No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5 Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, [redacted] Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, [redacted] Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, [redacted] (2 Constitution Square), [redacted] Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post Street [redacted]
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
[redacted] State Highway 161
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post [redacted]
San Francisco, CA 94104

7 Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8 Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9 Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

By Joseph Rannazzisi for

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit No. 192010	)	CASE NO: [redacted]
	)	
and	)	
	)	
MCKESSON DRUG COMPANY	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	
	)	
and	)	
	)	
MCKESSON DRUG CO.	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	
	)	
and	)	
	)	
MCKESSON CORPORATION	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against McKesson Corporation d/b/a McKesson Drug Company, McKesson Drug Company, McKesson Drug Co. and McKesson Corporation (hereinafter referred to collectively as "McKesson") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties through counsel have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The parties stipulate that McKesson denies the allegations of the Statement. The Board finds that McKesson permit numbers 192158, 191852, and 193420 violated the applicable provisions based upon the conduct set out in each and every Count of the Statement. The charges against permit number [redacted] shall be dismissed with prejudice.

2. McKesson shall pay to the Board an administrative fine in the amount of Fifteen Thousand dollars ($15,000.00) as to each applicable permit ([redacted] and [redacted]) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and McKesson shall not attempt to discharge the same in any bankruptcy proceeding.

3. That McKesson expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. McKesson further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, McKesson hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That McKesson agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That McKesson acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. McKesson acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the _____day of _____, 2018.

McKesson Corporation d/b/a McKesson Drug Company

By: _____
Its: Corporate Secretary

McKesson Drug Company

By: _____
Its: McKesson Corporate Secretary

McKesson Drug Co.

By: _____
Its: McKesson Corporate Secretary

McKesson Corporation

By: _____
Its: Corporate Secretary

_____
Roger N. Morris, Attorney for McKesson Corporation d/b/a/ McKesson Drug Company, McKesson Drug Company, McKesson Drug Co. and McKesson Corporation

DONE this the 24th day of May 2018.

ALABAMA STATE BOARD OF PHARMACY

By: _____
David Darby, R.Ph., President

By: _____
James S. Ward
Its Attorney

OF COUNSEL:
WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor Permit No. [redacted]	)	**CASE NO: [redacted]**
	)	
and	)	
	)	
MCKESSON DRUG COMPANY	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	
	)	
and	)	
	)	
MCKESSON DRUG CO.	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	
	)	
and	)	
	)	
MCKESSON CORPORATION	)	
	)	
Wholesale Distributor Permit No. [redacted]	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: McKesson Corporation d/b/a McKesson Drug Company
[redacted] Fraser Street
Aurora, Colorado 80011

McKesson Drug Company
[redacted] Kenskill Avenue
Washington, Ohio 43160

McKesson Drug Co.
[redacted] Plymouth Road
Livonia, MI 48150

McKesson Corporation
[redacted]Kendrick Lane
Lakeland, Florida 33805

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on June 26th, 2018 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate McKesson Corporation d/b/a McKesson Drug Company, McKesson Drug Company, McKesson Drug Co., and McKesson Corporation (hereinafter referred to collectively as "McKesson") as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that McKesson has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to

be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

COUNT ONE

As to Permit No. 191258, based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars ($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures

and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

COUNT TWO

As to Permit No. [redacted] based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars ($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

COUNT THREE

As to Permit No. [redacted] based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars

($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

COUNT FOUR

As to Permit No. [redacted] based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars ($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-

examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 16 day of February, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT A

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release ("Settlement Agreement" or "Agreement") is entered into between the United States of America, acting through the United States Department of Justice ("DOJ"),[1] and on behalf of the Drug Enforcement Administration ("DEA") (collectively referred to herein as the "United States"), and McKesson Corporation ("McKesson").

II. RECITALS

A. McKesson is a corporation organized and existing under the laws of the State of Delaware. McKesson's corporate headquarters and principal place of business is located at One Post Street, San Francisco, California.

B. McKesson is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. McKesson distributes pharmaceuticals through a network of distribution centers located throughout the United States, including distribution centers located in the following areas: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; La Crosse, Wisconsin; Lakeland, Florida; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California. McKesson formerly distributed pharmaceuticals through a distribution center located in Landover, Maryland, which closed in January 2012 (the "Landover Distribution Center"), and in La Vista, Nebraska, which closed in October 2016. A list of all McKesson U.S. Pharmaceutical distribution

[1] The Department of Justice is represented by the following 12 U.S. Attorney's Offices: Central District of California; Eastern District of California; District of Colorado; Middle District of Florida; Eastern District of Kentucky; Northern District of Illinois; District of Massachusetts; Eastern District of Michigan; District of Nebraska; District of New Jersey; Northern District of West Virginia; and Western District of Wisconsin.

centers that hold a DEA Certificate of Registration as of the Effective Date of this Agreement is attached hereto as Appendix A. Collectively, the distribution centers listed in Appendix A and the Landover Distribution Center are referred to herein as the "McKesson Distribution Centers."

C. At times relevant to this Agreement, the McKesson Distribution Centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* (the "CSA" or the "Act"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

D. The DEA is the DOJ component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

E. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

F. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. § 1301.74(b).

G. The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. § 1301.74(b). *See* 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

III. COVERED CONDUCT

The United States contends that it has certain civil claims against McKesson under 21 U.S.C. §§ 821, 823, 827, and 842(a)(5) for engaging in the following conduct (the "Covered Conduct") from January 1, 2009, through the Effective Date as that term is defined in Section

VI(F) (the "Covered Time Period"):

A. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations at McKesson Distribution Centers, including the following specific centers:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
La Crosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;
Washington Courthouse, Ohio; and
West Sacramento, California.

B. In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to herein as the "2008 Agreements") arising out of, among other things, McKesson's failure to report suspicious orders of controlled substances to the DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP") in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to the DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b).

C. McKesson failed to follow the procedures and policies set forth in the McKesson

CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP.

D. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers during the Covered Time Period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements.

E. McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined by the DEA in three letters from the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including McKesson, on September 27, 2006, February 7, 2007, and December 27, 2007.

F. Certain McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

IV. ACCEPTANCE OF RESPONSIBILITY

A. On or about September 27, 2006, February 7, 2007, and December 27, 2007, DEA's

Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum. The Compliance Addendum is an attachment to the Administrative Memorandum of Agreement (the "2017 MOA") entered into by McKesson and DEA contemporaneously with this Agreement. The Compliance Addendum and the 2017 MOA are attached hereto as Appendix B.

B. On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided, among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its CSMP. McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to

prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

V. TERMS AND CONDITIONS

In consideration of the mutual promises, covenants, and obligations set forth in this Settlement Agreement, the United States and McKesson agree as follows:

A. McKesson shall pay the United States the sum of One Hundred Fifty Million Dollars ($150,000,000.00) (the "Settlement Amount") within five (5) business days of the Effective Date of this Settlement Agreement, by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the United States.

B. In consideration of the fulfillment of the payment of the Settlement Amount, the United States agrees to:

1. Fully and finally release McKesson and all McKesson facilities, including McKesson subsidiary entities, affiliates, and registrants, (collectively, the "Released Parties") from any and all civil penalty claims under 21 U.S.C. § 842 that the United States could have asserted, or may assert in the future, against McKesson related to the Covered Conduct; and

2. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct.

C. Nothing in this Settlement Agreement shall prohibit or limit any other agency within DOJ or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any

component of DOJ, based on the Covered Conduct.

D. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the investigation and prosecution thereof by the United States.

E. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and the releases set forth herein, as to any entity or person (including McKesson) are the following:

1. Any potential criminal liability;

2. Any civil, criminal, or administrative liability arising under Title 26, United States Code (the Internal Revenue Code);

3. Any civil or administrative liability to the United States for any conduct other than the Covered Conduct, as described in paragraph III(A)-(F); and

4. Any liability based upon any obligation created by or arising under this Settlement Agreement.

F. Contemporaneously with the execution of this Settlement Agreement, McKesson will enter into the 2017 MOA, which will resolve administrative claims that DEA has or may have against McKesson related to the Covered Conduct. *See* Appendix B. McKesson acknowledges that it is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken, is taking, and will be taking further good faith actions to detect and prevent diversion. *See* Compliance Addendum attached hereto in Appendix B.

G. Nothing in this Settlement Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against McKesson for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct as described in Section III of this Settlement Agreement or which occur after the Effective Date of this Settlement Agreement.

H. McKesson agrees that any and all costs it has, will, or may incur in connection with this matter – including payment of the Settlement Amount under this Settlement Agreement, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action - shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

I. McKesson warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following its payment to the United States of the Settlement Amount. Furthermore, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to McKesson, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to

defraud any entity to which McKesson was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

J. If, within 91 days of the Effective Date of this Settlement Agreement or of any payment made hereunder, McKesson commences, or a third-party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (i) seeking to have any order for relief of McKesson's debts, or seeking to adjudicate McKesson as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for McKesson or for all or any substantial part of McKesson's assets, McKesson agrees as follows:

1. McKesson's obligations under this Settlement Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and McKesson will not argue or otherwise take the position in any such case, proceeding, or action that: (i) McKesson's obligations under this Settlement Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) McKesson was insolvent at the time this Settlement Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Settlement Agreement do not constitute a contemporaneous exchange for new value given to McKesson;

2. If McKesson's obligations under this Settlement Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Settlement Agreement, and bring any civil claims that would otherwise be covered by the release provided in Paragraph 2, above. McKesson agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that McKesson will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that McKesson will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought

by the United States within 90 calendar days of written notification to McKesson that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of the Settlement Agreement; and (iii) the United States may pursue any and all claims it had as of July 1, 2014, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

3. McKesson acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided by and through this Settlement Agreement.

K. Each Party to this Settlement Agreement will bear its own legal expenses and other costs incurred in connection with this matter, including those for the preparation and performance of this Settlement Agreement.

L. This Settlement Agreement is intended to be for the benefit of the Parties only.

M. McKesson represents that this Settlement Agreement is freely and voluntarily entered into, without any degree of duress or compulsion whatsoever. McKesson also acknowledges that it was represented by legal counsel of its choosing throughout the negotiation and execution of this Settlement Agreement.

N. McKesson consents to the disclosure of this Settlement Agreement, information about this Settlement Agreement, and the settlement memorialized herein by the United States to the public.

O. Nothing in this Settlement Agreement constitutes an agreement by the United States concerning characterization of the Settlement Amount for purposes of Title 26 of the United States Code (Internal Revenue Code).

VI. GENERAL PROVISIONS

A. Governing Law. This Settlement Agreement is governed by the laws of the United States of America. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties regarding this Settlement Agreement and its terms shall be the United States District Court for the Northern District of West Virginia.

B. Headings. The section and paragraph headings in this Settlement Agreement are inserted solely for the convenience of the Parties and shall not be construed to be part of or in any way affect the substantive provisions of this Settlement Agreement.

C. Merger Clause. This Settlement Agreement, including Attachments, constitutes the complete agreement and understanding by and between the United States and McKesson with respect to the settlement of claims against McKesson arising out of the Covered Conduct and no promises, agreements, or understandings, written or oral, not contained herein shall be of any force or effect. This Settlement Agreement may be amended at any time by mutual consent of the parties hereto, with any such amendment to be invalid, unless in writing, signed by an authorized agent of McKesson and an authorized representative of the United States.

D. Counterparts. This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

E. Binding. This Settlement Agreement is binding on McKesson and its successors, transferees, and assigns.

F. Effective Date: This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.

G. Drafting: For purposes of construing this Settlement Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

H. Authority to Sign: Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

IN WITNESS WHEREOF, the United States and McKesson have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

THE UNITED STATES OF AMERICA

Dated: 12/30/2016

William J. Ihlenfeld, II
U.S. Attorney
Northern District of West Virginia

Dated: 1/17/17

Robert C. Troyer
Acting U.S. Attorney
District of Colorado

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

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_____
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Eastern District of Michigan

Dated. _____

_____
Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: 01-05-17

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

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Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: 1-6-17

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: 1/4/17

Deborah R. Gilg
U.S. Attorney
District of Nebraska

Dated: _____

Phillip A. Talbert
U.S. Attorney
Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: _____

Paul J. Fishman
U.S. Attorney
District of New Jersey

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Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: 1/4/17

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: 1-5-17

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

_____
A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: 1/5/17

_____
Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

_____
Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

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U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: 1/5/17

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

McKESSON CORPORATION

Dated: 1/5/17

Lori A. Schechter
Executive Vice President, General Counsel and
Chief Compliance Officer for
McKesson Corporation

Dated: 1/5/17

Geoffrey E. Hobart
Covington & Burling LLP
Counsel for McKesson Corporation

EXHIBIT B

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at [redacted] East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration [redacted]

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration [redacted], located at [redacted] Kenskill Avenue, Washington Court House, Ohio [redacted] McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at [redacted] Plymouth Road, Livonia, Michigan [redacted] McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration [redacted], located at 1515 Kendrick Lane, Lakeland, Florida [redacted] McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration [redacted] located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration [redacted] located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration [redacted] located at [redacted] Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

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distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration [redacted] located at [redacted] Airport Road, LaCrosse, Wisconsin [redacted] McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration [redacted] located at [redacted] South [redacted] Street, La Vista, Nebraska [redacted] McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration [redacted] located at [redacted] McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration [redacted] located at [redacted] Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2 Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4 Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5 Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination

II Terms and Conditions

1 Obligations of McKesson

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration numbe[redacted]

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration [redacted], will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number [redacted] McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, [redacted] Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration [redacted] for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II 1 e-g.

Division, Diversion Regulatory Unit, [redacted] Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration [redacted] for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the [redacted] of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, [redacted] North Commerce Parkway, Weston, Florida [redacted] a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration [redacted] for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, e.g., administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration [redacted], and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration [redacted] to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or

e. Any liability based upon any obligation created by or arising under this Agreement

III. Miscellaneous

1 Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3 No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5 Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, [redacted] Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, [redacted] Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, [redacted] (2 Constitution Square), 2nd Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post [redacted]
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
[redacted] Highway 161
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post Street [redacted]
San Francisco, CA 94104

7 Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8 Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9 Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

10. Authorizations. The Individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION** [redacted]Kenskill Ave. Washington Court House, OH 43160 **Out of State Distributor License No. OSD 3275** and **MCKESSON DRUG CO.** [redacted] Plymouth Rd. Livonia, MI 48150 **Out of State Distributor License No. OSD 4086** Respondents.	Case No. [redacted] OAH No. [redacted]

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463
Board of Pharmacy

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527- 4475

[redacted]

June 10, 2019

Certified Article Number
9414 7266 9904 2125 4356 58
SENDER'S RECORD
Return receipt requested

Scott Miller, Pharmacist-in-Charge
Mckesson Drug Company
3000 Kenskill Avenue
Washington Court House, OH 43160

RE: Case Number [redacted]

Dear Mr. Miller:

Enclosed is a certified true copy of the Consent Order entered by the Virginia Board of Pharmacy ("Board"), which resolves this matter.

This Order will be forwarded to Rose Dematteo, Compliance Case Manager for the Board of Pharmacy. Ms. Dematteo will monitor your compliance with the terms of the Order on behalf of the Board. Please direct all questions, documents, and correspondence related to your compliance with your Order to Ms. Dematteo at [redacted] or directly to her by mail at the Board of Pharmacy, Perimeter Center, [redacted] Mayland Drive, Suite 300, Henrico, Virginia [redacted]

Should you have any questions or concerns regarding this matter, please contact our office at [redacted]

Sincerely,

Caroline D. Juran, RPh, DPh
Executive Director
Virginia Board of Pharmacy

cc: Anne Joseph, Deputy Director, Administrative Proceedings Division
Rose Dematteo, Compliance Case Manager
Susan Brooks, Operations Manager, Administrative Proceedings Division
Nicholas H. Meza, Attorney
David E. Brown, D.C., Director, Department of Health Professions
Barbara Allison-Bryan, M.D., Chief Deputy Director, Department of Health Professions

JUN 0 7 2019
DHP

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: **MCKESSON DRUG COMPANY**
Permit Number: [redacted]
Case Number:

CONSENT ORDER

JURISDICTION AND PROCEDURAL HISTORY

The Virginia Board of Pharmacy ("Board") and Scott Miller, authorized representative, McKesson Drug Company, as evidenced by their signatures hereto, in lieu of proceeding to an informal conference, enter into the following Consent Order affecting McKesson Drug Company's permit to operate as a non-resident wholesale distributor in the Commonwealth of Virginia.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On 2/25/1997, the Board issued Permit Number [redacted] to McKesson Drug Company ("McKesson") to operate as a non-resident wholesale distributor in the Commonwealth of Virginia. Said permit is scheduled to expire on 2/29/2020. At all times relevant hereto, said permit was in full force and effect.

2. McKesson violated Virginia Code § 54.1-3316(8) in that on January 17, 2017, by settlement with the United States Drug Enforcement Administration ("DEA"), McKesson's authority to distribute controlled substances from its Washington Court House, Ohio, distribution center, DEA Certificate of Registration [redacted] was suspended for a period of two years from February 16, 2019 to February 16, 2021. Not included in this suspension was McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Washington Court House, Ohio, distribution center, which are authorized under DEA registration number [redacted] Also not included in this suspension was McKesson's authority to, at its option, continue to possess and

distribute controlled substances to federal customers that purchase controlled substances from McKesson's Washington Court House, Ohio, distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

3. McKesson violated Virginia Code § 54.1-3316(10) in that on October 17, 2017, by Consent Agreement, the Louisiana Board of Pharmacy suspended McKesson's Louisiana Controlled Dangerous Substance License for McKesson's Washington Court House, Ohio, distribution center from January 18, 2019 to January 18, 2021. The action by the Louisiana Board of Pharmacy did not include the suspension of McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Washington Court House, Ohio, distribution center, which are authorized under DEA registration number [redacted] These Actions also did not affect McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson's Washington Court House, Ohio, distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

CONSENT

McKesson Drug Company, by affixing the signature of a representative hereon to this Order, agrees to the following:

1. McKesson has been advised to seek advice of counsel prior to signing this document and is represented by Roger Morris, Esq.;

2. McKesson is fully aware that without its consent, no legal action can be taken against it or its permit except pursuant to the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*;

3. McKesson acknowledges that it has the following rights, among others: the right to an informal fact-finding conference before the Board; and the right to representation by counsel;

4. McKesson waives its right to an informal conference;

5. McKesson admits to the Findings of Fact and Conclusions of Law contained herein and waives its right to contest such Findings of Fact and Conclusions of Law and any sanction imposed hereunder in any future judicial or administrative proceeding in which the Board is a party;

6. McKesson consents to the entry of the following Order affecting its right to operate as a non-resident wholesale distributor in the Commonwealth of Virginia.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS as follows:

1. McKesson Drug Company shall not distribute Schedule II-V controlled substances from its Washington Court House, Ohio, distribution center into the Commonwealth of Virginia from the date of entry of this Order until February 16, 2021. This restriction shall not apply to or limit McKesson's authority to distribute, or operations involving, List 1 Chemical products at or from the Washington Court House, Ohio, distribution center, which are authorized under the DEA registration number [redacted] This restriction also shall not apply to or limit McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson's Washington Court House, Ohio, distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

2. McKesson Drug Company shall comply with all laws and regulations governing the practice of a non-resident wholesale distributor in the Commonwealth of Virginia.

3. Any violation of the foregoing terms and conditions of this Order or any statute or regulation governing the practice of a non-resident wholesale distributor shall constitute grounds for further disciplinary action.

Pursuant to Virginia Code §§ [redacted] and [redacted] the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran, RPh, DPh
Executive Director
Virginia Board of Pharmacy

ENTERED: 6/10/19

SEEN AND AGREED TO:

Todd Spaulding
~~Scott Miller~~, representative for
McKesson Drug Company

~~COMMONWEALTH OF VIRGINIA~~
COUNTY/CITY OF Fayette Co Ohio, TO WIT:

Subscribed and sworn to before me, a notary public in and for the Commonwealth of Virginia at large, on this 31st day of May, 2019.

Notary Public

My commission expires: Dec 6 2020

Registration No.:

NOTARY PUBLIC STATE OF OHIO

SANDRA L. HELSEL
Notary Public, State of Ohio
My Commission Expires
December 6, 2020

CERTIFIED TRUE COPY
BY:
VIRGINIA BOARD OF PHARMACY

This Decision shall become effective at 5:00 p.m. on August 28, 2019.

It is so ORDERED on July 29, 2019.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Greg Lippe
Board Vice President (Acting President)

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
KEVIN W. BELL
Deputy Attorney General
State Bar No. 192063
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7511
Facsimile: (916) 327-8643
E-mail: Kevin.Bell@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION** **3000 Kenskill Ave.** **Washington Court House, OH 43160** **Out of State Distributor License** **No. OSD 3275** **And** **MCKESSON DRUG CO.** **[redacted] Plymouth Rd.** **Livonia, MI 48150** **Out of State Distributor License** **No. OSD 4086** Respondents.	Case No. [redacted] OAH No. [redacted] **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Interim Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Kevin W. Bell, Deputy Attorney General.

2. Respondent John Hammergren[1], McKesson Corporation and McKesson Drug Co. (Respondents) are represented in this proceeding by attorney Alissa Brice Castaneda, whose address is: Renaissance One, Two North Central Avenue, Phoenix, AZ 85004-2391.

JURISDICTION

3. On or about August 11, 2000, the Board issued Out of State Distributor License No. [redacted] to John Hammergren, McKesson Corporation, and Out of State Distributor License No. OSD[redacted] to John Hammergren, McKesson Drug Co. The Out of State Distributor Licenses were in full force and effect at all times relevant to the charges brought in Accusation No. 6413 and will expire on August 1, 2020, unless renewed.

4. First Amended Accusation No. 6413 was filed before the Board and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on May 15, 2019. Respondents timely filed his Notice of Defense contesting the Accusation. A copy of First Amended Accusation No. 6413 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 6413. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at their own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

[1] The Board has recently discovered that John Hammergren, CEO of both Respondents McKesson Corporation and McKesson Drug Company, disassociated with Respondents on April 1, 2019. Because Respondents have not provided the identity of the new CEO, John Hammergren remains as the CEO of record.

7. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

8. Respondents understand and agree that the charges and allegations in First Amended Accusation No. 6413, if proven at a hearing, constitute cause for imposing discipline upon their Out of State Distributor Licenses.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondents hereby give up their right to contest the charges in the First Amended Accusation.

10. Respondents agree that their Out of State Distributor Licenses are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

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13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. This Stipulated Settlement and Disciplinary Order is dispositive of any and all known and extant violations of California law that the Board of Pharmacy has asserted or could have asserted against Respondents relating to the 2017 DEA Settlement and underlying facts. It is the complete, final, and exclusive embodiment of claims related to First Amended Accusation No. 6413, including any past or future nondisciplinary or disciplinary actions taken by other Federal or state entities related to the 2017 DEA Settlement referenced in the First Amended Accusation and underlying facts.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Out of State Distributor License No. [redacted] issued to John Hammergren, McKesson Corporation, and Out of State Distributor License No. OSD [redacted] issued to John Hammergren, McKesson Drug Co. shall be publicly REPROVED by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. [redacted], attached as exhibit A.

Cost Recovery. Respondents shall pay $4,000.00 to the Board, jointly and severally, for its costs associated with the investigation and enforcement of this matter. Respondents shall be permitted to pay these costs in a payment plan approved by the Board. If Respondents fail to pay the Board costs as ordered, Respondents shall not be allowed to renew their Out of State Distributor Licenses until Respondents pay costs in full.

Community Service. Respondents shall provide $1.5 million (wholesale value) worth of Naloxone, jointly and severally, to be distributed at no charge to California entities such as First Responders or to similar non-profit entities.

Respondents must submit to the Board within 120 days of the effective date of the Order a proposal for the distribution of the Naloxone. The proposal must specify the entities within California that will receive the Naloxone, the manner and timing in which the entities will receive the Naloxone, and the quantities of Naloxone distributed to each entity. Respondents will determine at their sole discretion the manner and timing in which the entities will receive the Naloxone, and the quantities of Naloxone distributed to each entity.

Respondents shall submit to the Board a report every six months detailing the progress in distributing the Naloxone, which shall include the names of the entities to which the Naloxone has been distributed and the quantities of Naloxone distributed. The first report shall be due 180 days after Respondents' proposal has been submitted to the Board.

This community service requirement shall be completed within 4 years of the effective date of the Order.

Failure to abide by any term of this Disciplinary Order shall constitute grounds for discipline against Respondents, up to and including Revocation.

ACCEPTANCE

Respondents have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with their attorney, Alissa Brice Castaneda. Respondents understand the stipulation and the effect it will have on the Out-of State Distributor License No. OSD 3275, and Out of State Distributor License No. OSD 4086. Respondents enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: May 23, 2019

for MCKESSON CORPORATION
and MCKESSON DRUG CO.
Respondents

I have read and fully discussed with Respondent John Hammergren, McKesson Corporation/McKesson Drug Co. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 5/21/19

Alissa Brice Castaneda
Attorney for Respondents

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5/21/19

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

KEVIN W. BELL
Deputy Attorney General
Attorneys for Complainant

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Facsimile: (916) 327-8643
E-mail: Kevin.Bell@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION** **[redacted] Kenskill Ave.** **Washington Court House, OH 43160** **Out of State Distributor License No. OSD 3275** **And** **MCKESSON DRUG CO.** **[redacted] Plymouth Rd.** **Livonia, MI 48150** **Out of State Distributor License No. OSD 4086** Respondents.	Case No. [redacted] OAH No. [redacted] **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Ann Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Interim Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about August 11, 2000, the Board issued Out of State Distributor License Number OSD 3275 to McKesson Corporation, John Hammergren, CEO[1]. The License will expire on August 1, 2019 unless otherwise renewed.

3. On or about July 1, 2002, the Board issued Out of State Distributor License Number OSD 4086 to McKesson Corporation to do business as McKesson Drug Co., John Hammergren, CEO. The License will expire on July 1, 2019, unless otherwise renewed.

REGULATORY AND STATUTORY AUTHORITY

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 141 of the Code states:

> (a) For any licensee holding a license issued by a board under the jurisdiction of the department, a disciplinary action taken by another state, by any agency of the federal government, or by another country for any act substantially related to the practice regulated by the California license, may be a ground for disciplinary action by the respective state licensing board. A certified copy of the record of the disciplinary action taken against the licensee by another state, an agency of the federal government, or another country shall be conclusive evidence of the events related therein.
>
> (b) Nothing in this section shall preclude a board from applying a specific statutory provision in the licensing act administered by that board that provides for discipline based upon a disciplinary action taken against the licensee by another state, an agency of the federal government, or another country.

6. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board . . .whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.

[1] The Board has recently discovered that John Hammergren, CEO of both Respondents McKesson Corporation and McKesson Drug Company, disassociated with Respondents on April 1, 2019. Because Respondents have not provided the identity of the new CEO, John Hammergren remains as the CEO of record.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

7. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

8. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

. . . ."

COST RECOVERY

9. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

10. Respondents McKesson Corporation and McKesson Drug Co are subject to disciplinary action under section 4301(o) for violating or attempting to violate, directly or

indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency. The circumstances are as follows:

11. On or about May 2, 2008, Respondents entered into an Administrative Memorandum of Agreement (2008 MOA) with the United States Drug Enforcement Administration (DEA). The MOA provided, amongst other things, that Respondents maintain a compliance program designed to detect and prevent the diversion of controlled substances, and inform the DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b).

12. On or about January 17, 2017, Respondents entered into a Settlement Agreement with the United States Department of Justice and the DEA. In the Settlement Agreement, Respondents acknowledged that, at various times during the period covered by the Settlement Agreement, it did not identify or report to the DEA certain orders placed by certain pharmacies which should have been detected as suspicious in a manner fully consistent with the requirements set forth on the 2008 MOA, and based on the guidance contained in letters sent by the DEA about the requirements of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a part of the Settlement Agreement, Respondents agreed to pay $150 million to the United States, and the DEA suspended the DEA registration of Respondent McKesson Corporation (OSD3275) from January 18, 2019 to January 18, 2021, and suspended Respondent McKesson Drug Co. (OSD4086) from January 17, 2017 to January 17, 2019.

SECOND CAUSE FOR DISCIPLINE

(Discipline by an Agency of the Federal Government and/or Another State)

13. Respondents McKesson Corporation and McKesson Drug Co are subject to disciplinary action under sections 141 and 4301 (n) for a disciplinary action taken by any agency of the federal government and by another state for any act substantially related to the practice regulated by the California license, as set forth in paragraph 12 above and incorporated by reference. In addition to the disciplinary action taken by the federal government, other state regulatory agencies disciplined Respondents for violations of state laws or regulations as a result

the disciplinary action taken by the federal government. Those states include, but are not limited to the following: the Idaho Board of Pharmacy, Case Nos. [redacted] and [redacted] and the State of Oregon, Board of Pharmacy, Case No. [redacted]

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoke or Suspend Out of State Distributor License Number OSD 3275, issued to Respondent McKesson Corporation, John Hammergren, CEO;

2. Revoke or Suspend Out of State Distributor License Number OSD 4086, issued to Respondent McKesson Drug Co., John Hammergren, CEO;

3. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

4. Taking such other and further action as deemed necessary and proper.

DATED: May 15, 2019

Anne Sodergren

Anne Sodergren
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION** [redacted]Kenskill Ave. Washington Court House, OH 43160 **Out of State Distributor License No.** **OSD 3275** and **MCKESSON DRUG CO.** [redacted]Plymouth Rd. Livonia, MI 48150 **Out of State Distributor License No.** **OSD 4086** Respondents.	Case No. [redacted] OAH No. [redacted]

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on August 28, 2019.

It is so ORDERED on July 29, 2019.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Greg Lippe
Board Vice President (Acting President)

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
KEVIN W. BELL
Deputy Attorney General
State Bar No. 192063
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7511
Facsimile: (916) 327-8643
E-mail: Kevin.Bell@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION** **[redacted] Kenskill Ave.** **Washington Court House, OH 43160** **Out of State Distributor License No. OSD 3275** **And** **MCKESSON DRUG CO.** **[redacted] Plymouth Rd.** **Livonia, MI 48150** **Out of State Distributor License No. OSD 4086** Respondents.	Case No [redacted] OAH No. [redacted] **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Interim Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Kevin W. Bell, Deputy Attorney General.

2. Respondent John Hammergren[1], McKesson Corporation and McKesson Drug Co. (Respondents) are represented in this proceeding by attorney Alissa Brice Castaneda, whose address is: Renaissance One, Two North Central Avenue, Phoenix, AZ 85004-2391.

JURISDICTION

3. On or about August 11, 2000, the Board issued Out of State Distributor License No. OSD 3275 to John Hammergren, McKesson Corporation, and Out of State Distributor License No. OSD 4086 to John Hammergren, McKesson Drug Co. The Out of State Distributor Licenses were in full force and effect at all times relevant to the charges brought in Accusation No. 6413 and will expire on August 1, 2020, unless renewed.

4. First Amended Accusation No. 6413 was filed before the Board and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on May 15, 2019. Respondents timely filed his Notice of Defense contesting the Accusation. A copy of First Amended Accusation No. 6413 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 6413. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at their own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

[1] The Board has recently discovered that John Hammergren, CEO of both Respondents McKesson Corporation and McKesson Drug Company, disassociated with Respondents on April 1, 2019. Because Respondents have not provided the identity of the new CEO, John Hammergren remains as the CEO of record.

7. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

8. Respondents understand and agree that the charges and allegations in First Amended Accusation No. 6413, if proven at a hearing, constitute cause for imposing discipline upon their Out of State Distributor Licenses.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondents hereby give up their right to contest the charges in the First Amended Accusation.

10. Respondents agree that their Out of State Distributor Licenses are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

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13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. This Stipulated Settlement and Disciplinary Order is dispositive of any and all known and extant violations of California law that the Board of Pharmacy has asserted or could have asserted against Respondents relating to the 2017 DEA Settlement and underlying facts. It is the complete, final, and exclusive embodiment of claims related to First Amended Accusation No. 6413, including any past or future nondisciplinary or disciplinary actions taken by other Federal or state entities related to the 2017 DEA Settlement referenced in the First Amended Accusation and underlying facts.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Out of State Distributor License No. OSD 3275 issued to John Hammergren, McKesson Corporation, and Out of State Distributor License No. OSD 4086 issued to John Hammergren, McKesson Drug Co. shall be publicly REPROVED by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6413, attached as exhibit A.

Cost Recovery. Respondents shall pay $4,000.00 to the Board, jointly and severally, for its costs associated with the investigation and enforcement of this matter. Respondents shall be permitted to pay these costs in a payment plan approved by the Board. If Respondents fail to pay the Board costs as ordered, Respondents shall not be allowed to renew their Out of State Distributor Licenses until Respondents pay costs in full.

Community Service. Respondents shall provide $1.5 million (wholesale value) worth of Naloxone, jointly and severally, to be distributed at no charge to California entities such as First Responders or to similar non-profit entities.

Respondents must submit to the Board within 120 days of the effective date of the Order a proposal for the distribution of the Naloxone. The proposal must specify the entities within California that will receive the Naloxone, the manner and timing in which the entities will receive the Naloxone, and the quantities of Naloxone distributed to each entity. Respondents will determine at their sole discretion the manner and timing in which the entities will receive the Naloxone, and the quantities of Naloxone distributed to each entity.

Respondents shall submit to the Board a report every six months detailing the progress in distributing the Naloxone, which shall include the names of the entities to which the Naloxone has been distributed and the quantities of Naloxone distributed. The first report shall be due 180 days after Respondents' proposal has been submitted to the Board.

This community service requirement shall be completed within 4 years of the effective date of the Order.

Failure to abide by any term of this Disciplinary Order shall constitute grounds for discipline against Respondents, up to and including Revocation.

ACCEPTANCE

Respondents have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with their attorney, Alissa Brice Castaneda. Respondents understand the stipulation and the effect it will have on the Out of State Distributor License No. OSD 3275, and Out of State Distributor License No. OSD 4086. Respondents enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: May 23, 2019

for MCKESSON CORPORATION
and MCKESSON DRUG CO.
Respondents

I have read and fully discussed with Respondent John Hammergren, McKesson Corporation/McKesson Drug Co. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 5/21/19

Alissa Brice Castaneda
Attorney for Respondents

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5/21/19

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

KEVIN W. BELL
Deputy Attorney General
Attorneys for Complainant

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Sacramento, CA 94244-2550
Telephone: (916) 210-7511
Facsimile: (916) 327-8643
E-mail: Kevin.Bell@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION** **[redacted] Kenskill Ave.** **Washington Court House, OH 43160** **Out of State Distributor License No. OSD 3275** **And** **MCKESSON DRUG CO.** **[redacted] Plymouth Rd.** **Livonia, MI 48150** **Out of State Distributor License No. OSD 4086** Respondents.	Case No. [redacted] OAH No. [redacted] **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Ann Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Interim Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about August 11, 2000, the Board issued Out of State Distributor License Number OSD 3275 to McKesson Corporation, John Hammergren, CEO[1]. The License will expire on August 1, 2019 unless otherwise renewed.

3. On or about July 1, 2002, the Board issued Out of State Distributor License Number OSD 4086 to McKesson Corporation to do business as McKesson Drug Co., John Hammergren, CEO. The License will expire on July 1, 2019, unless otherwise renewed.

REGULATORY AND STATUTORY AUTHORITY

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 141 of the Code states:

> (a) For any licensee holding a license issued by a board under the jurisdiction of the department, a disciplinary action taken by another state, by any agency of the federal government, or by another country for any act substantially related to the practice regulated by the California license, may be a ground for disciplinary action by the respective state licensing board. A certified copy of the record of the disciplinary action taken against the licensee by another state, an agency of the federal government, or another country shall be conclusive evidence of the events related therein.
>
> (b) Nothing in this section shall preclude a board from applying a specific statutory provision in the licensing act administered by that board that provides for discipline based upon a disciplinary action taken against the licensee by another state, an agency of the federal government, or another country.

6. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board . . .whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.

[1] The Board has recently discovered that John Hammergren, CEO of both Respondents McKesson Corporation and McKesson Drug Company, disassociated with Respondents on April 1, 2019. Because Respondents have not provided the identity of the new CEO, John Hammergren remains as the CEO of record.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

7. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

8. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

. . . ."

COST RECOVERY

9. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

10. Respondents McKesson Corporation and McKesson Drug Co are subject to disciplinary action under section 4301(o) for violating or attempting to violate, directly or

indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency. The circumstances are as follows:

11. On or about May 2, 2008, Respondents entered into an Administrative Memorandum of Agreement (2008 MOA) with the United States Drug Enforcement Administration (DEA). The MOA provided, amongst other things, that Respondents maintain a compliance program designed to detect and prevent the diversion of controlled substances, and inform the DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b).

12. On or about January 17, 2017, Respondents entered into a Settlement Agreement with the United States Department of Justice and the DEA. In the Settlement Agreement, Respondents acknowledged that, at various times during the period covered by the Settlement Agreement, it did not identify or report to the DEA certain orders placed by certain pharmacies which should have been detected as suspicious in a manner fully consistent with the requirements set forth on the 2008 MOA, and based on the guidance contained in letters sent by the DEA about the requirements of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a part of the Settlement Agreement, Respondents agreed to pay $150 million to the United States, and the DEA suspended the DEA registration of Respondent McKesson Corporation (OSD3275) from January 18, 2019 to January 18, 2021, and suspended Respondent McKesson Drug Co. (OSD4086) from January 17, 2017 to January 17, 2019.

SECOND CAUSE FOR DISCIPLINE

(Discipline by an Agency of the Federal Government and/or Another State)

13. Respondents McKesson Corporation and McKesson Drug Co are subject to disciplinary action under sections 141 and 4301 (n) for a disciplinary action taken by any agency of the federal government and by another state for any act substantially related to the practice regulated by the California license, as set forth in paragraph 12 above and incorporated by reference. In addition to the disciplinary action taken by the federal government, other state regulatory agencies disciplined Respondents for violations of state laws or regulations as a result

the disciplinary action taken by the federal government. Those states include, but are not limited to the following: the Idaho Board of Pharmacy, Case Nos. BOP 17-054 and BOP 17-055; and the State of Oregon, Board of Pharmacy, Case No. 2017-0291.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoke or Suspend Out of State Distributor License Number OSD 3275, issued to Respondent McKesson Corporation, John Hammergren, CEO;

2. Revoke or Suspend Out of State Distributor License Number OSD 4086, issued to Respondent McKesson Drug Co., John Hammergren, CEO;

3. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

4. Taking such other and further action as deemed necessary and proper.

DATED: May 15, 2019

Anne Sodergren

Anne Sodergren
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2018101253
McKessonFirstAmACC.docx

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

October 17, 2019

McKesson Corporation
[redacted] McKesson Street, Suite 101
Aurora, IL 60502-7703

Sent via email: [redacted]

RE: Case No. [redacted] Stipulation and Final Agency Order

Dear Pharmacy Manager:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the terms and conditions of the above listed Stipulation and Final Agency Order effective October 4, 2019.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released you from the terms and conditions of the October 4, 2019, Stipulation and Final Agency Order and restored your Registration No. [redacted] to unencumbered status.

Although this disciplinary action will remain a public document, our records show that the requirements of your Order are complete. Please retain this letter for your records.

Your cooperation during the pendency of this matter is sincerely appreciated.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Dmitry Kunin
Program Director

cc: File

McKESSON

August 9, 2019

VIA E-MAIL ONLY - [redacted]

Lana Hyatte
Program Specialist
Colorado State Board of Pharmacy
Colorado Department of Regulatory Agencies
Division of Professions and Occupations
1560 Broadway
Suite 1350
Denver Colorado, CO 80202

RE: License Number: [redacted]
Case Number: [redacted]

Dear Ms. Hyatte:

This letter is McKesson Corporation's ("McKesson") response to the Colorado State Board of Pharmacy's ("Board") July 24, 2019[1] Complaint (Case Number: 2019-5119). The Complaint alleges that McKesson's Chicagoland, Illinois distribution center (License Number: [redacted] failed to provide timely notice of a change in the Designated Representative in violation of Colo. Code Regs. [redacted]c). I acknowledge the untimely notification and sincerely apologize for the oversight. As explained below, procedures were in place to properly notify the Board of the change. However, there was an internal misunderstanding of the need to submit background check results with the notice of change that led to the untimely notification.

I assumed the duties of Designated Representative of the Chicagoland distribution center in place of Robert Perrich on May 1, 2019. Upon the change, our internal licensing team prepared all required notices to state boards and regulatory authorities, including Colorado. These notices and forms were sent to me for my final review. Upon my review and signature, the notices were mailed to the respective boards. Unfortunately, this was not the case with Colorado. Our internal licensing team was under the impression that we needed to receive the fingerprint results from IdentoGo before we could submit the Change of Designated Representative application to the Board.

On July 7, 2019, I received a phone call from the Colorado Bureau of Investigations to let me know they had received the fingerprint cards but the results had not yet been "pulled" by the Board. It was not until then that I realized our licensing team had not sent the Change of

[1] Please note, the Board's letter, which was sent to McKesson via email on July 24, 2019, is erroneously dated as June 3, 2019.

Designated Representative application to the Board. Upon discovery we immediately took steps to correct the problem and submitted the application that same day.

Again, I acknowledge the untimely notification and sincerely apologize for this oversight. I understand the notification requirements under the law and I take my responsibility as Designated Representative seriously. McKesson has appropriate procedures in place to ensure compliance with applicable laws and regulations. Our failure to provide timely notice to the Board in this instance was due to human error and a misunderstanding.

I look forward to working with the Board to promptly resolve this matter. If you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

Nicholas Davis

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case [redacted]

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MCKESSON CORPORATION, REGISTRATION NO. [redacted]

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and McKesson Corporation ("Respondent Outlet") to resolve all matters pertaining to Board Case Number [redacted] as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an out-of-state prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2018).

2. Respondent Outlet was originally registered in the State of Colorado on or about January 24, 2007, being issued registration [redacted], and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 1995 McKesson St, Ste 101, Aurora, IL 60502.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit to the Board an application detailing a change in designated representative and fee. In this case, 76 days transpired between May 1, 2019, the date the previous designated representative ceased the position, and July 16, 2019, the date the application and fee were received.

6. On or about July 24, 2019, the Board initiated a complaint against Respondent Outlet because of the delay of 76 days in submitting an application detailing a change in designated representative and fee.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

[redacted] **Unprofessional conduct - grounds for discipline.**

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board.

* * *

Pharmacy Board Rules and Regulations

[redacted]**Change of name, location, or ownership, or designated representative.**

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. Fine with Surcharge. Pursuant to section 12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of **One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00)**. The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board.

9. Compliance. Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to sections 12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under section 12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension

or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability**. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record**. Upon execution by all parties, this Stipulation and Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Effective Date**. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

Ammie McAsey

Authorized Representative

Dated: October 2, 2019

Ammie McAsey / SVP, Distribution Operations

Name / Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this _____day of _____, 2019.

State Board of Pharmacy

BY: _____
Dmitry Kunin
Program Director

McKESSON

August 29, 2019

Lana Hyatte
Program Specialist
Colorado State Board of Pharmacy
Colorado Department of Regulatory Agencies
Division of Professions and Occupations
1560 Broadway
Suite 1350
Denver Colorado, CO 80202

RE: License Number: [redacted]
Case Number: [redacted]

Dear Ms. Hyatte:

Enclosed with this letter please find payment of $1,1500 (check number: 0192627) to Case No. [redacted] and the copy of the Stipulation and Final Agency Order as requested.

Please contact me at your earliest convenience if you have further questions about this matter.

Very truly yours,

Beatrix Erdei
McKesson Corporation
Tel: [redacted]
Email: [redacted]

McKESSON

McKesson Corporation
6555 North State Hwy 161
Irving, TX 75039

SUMMARY

CHECK NUMBER:	0192627
Check Date:	08/27/2019
CHECK AMOUNT:	$1,150.00

14582733 - 00006

COLORADO STATE BOARD OF PHCY
OFFICE OF LICENSING PHCY
[redacted]BROADWAY STE 1350
DENVER, CO 802025143

Invoice Date	Reference Number	Net Amount	Gross Amount	Discount Amount
20190819 20190827	CO-8144 CHK PAID VENDOR # 3000008120	$1,150.00	$1,150.00	$0.00
TOTAL		**$1,150.00**	**$1,150.00**	**$0.00**

THE FACE OF THIS DOCUMENT HAS A COLORED BACKGROUND. SECURITY FEATURES INCLUDE THERMOCHROMIC INK, MICROPRINTING, A VOID PANTOGRAPH, AND AN ARTIFICIAL WATERMARK AND SECURITY SCREEN ON THE BACK.

McKESSON

McKesson Corporation
6555 North State Hwy 161
Irving TX 75039

75-1592/912

Check Number	Date
[redacted]	08/27/2019

Amount
$******1,150.00

PAY EXACTLY ********1,150* DOLLARS AND * 00 * CENTS

TO THE ORDER OF:

COLORADO STATE BOARD OF PHCY
OFFICE OF LICENSING PHCY
[redacted] STE 1350
DENVER, CO 802025143

usbank.

VOID VOID VOID

⑈0000192627⑈ ⑆091215927⑆152100013019⑈

BEFORE THE IOWA BOARD OF PHARMACY

RE: Wholesaler License and Controlled Substances Act Registration of **MCKESSON DRUG COMPANY** License No. 7987 Registration No. 2212001 Respondent	CASE NO. [redacted] **COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER**

COME NOW the Iowa Board of Pharmacy ("Board") and McKesson Drug Company ("Respondent"), 2101 12th Ave S, Clear Lake IA 50428, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4), and 657 IAC 35.5. The Board has jurisdiction over Respondent and the subject matter of this case pursuant to Iowa Code chapters 17A, 124, 155A, and 272C (2019), and 657 IAC 36.

A. STATEMENT OF CHARGES

COUNT I
FAILURE TO TAKE COMPLETE INVENTORY

1. Respondent is charged with failing to comply with the requirements in 657 IAC 10.19 to take a complete and accurate inventory of all stocks of controlled substances, and may be disciplined pursuant to Iowa Code sections 124.304(1)(d) and 155A.17(4), and 657 IAC 10.44(5), 36.6(28).

B. FACTUAL CIRCUMSTANCES

2. Respondent's wholesaler license number 7987 is currently active through December 31, 2019. Respondent's Controlled Substances Act registration number 2212001 is currently active through January 31, 2021.

3. Respondent failed to include pseudoephedrine products in the annual controlled substance inventory.

4. Respondent failed to take an initial inventory of butalbital products after such products became schedule III controlled substances on June 26, 2019.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

5. The Board has jurisdiction over the parties and the subject matter of these proceedings.

6. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

7. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

8. Respondent acknowledges that it has the right to be represented by counsel on this matter.

9. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

10. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

11. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

12. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank. These reports shall be the only reports or publications the Board will make regarding this settlement.

13. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

14. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

15. Respondent is hereby **CITED** for failing to comply with the requirements in 657 IAC 10.19 to take a complete and accurate inventory of all stocks of controlled substances and **WARNED** that future violations of the laws and rules governing wholesalers can result in further disciplinary action.

16. Respondent shall pay a **CIVIL PENALTY** in the amount of five thousand dollars ($5,000) within sixty (60) days of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309.

17. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C and 657 IAC 36.

By the signature below, Ammie McAsey acknowledges s/he is the SVP Distribution Operations for Respondent and is authorized to sign this Combined Statement of Charges, Settlement Agreement, and Final Order on behalf of Respondent.

1-2-2020
Date

Ammie McAsey
MCKESSON DRUG COMPANY
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 1 day of January, 2020.

Tasia Howard
Chairperson
Iowa Board of Pharmacy

Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D.
EXECUTIVE DIRECTOR

ACCEPTANCE OF SERVICE BY ATTORNEY

I, Roger Morris,
(Print name)

as attorney for McKesson Drug Company, acknowledge that I received a copy of the Combined Statement of Charges, Settlement Agreement, and Final Order dated January 7, 2020 and am authorized to accept service of this document on behalf of McKesson Drug Company.

By signing this form, I acknowledge that I am accepting service of the document described above.

(Signature) 1/15/2020 (Date)

Please return this form by mail to the address below, by fax to the number below, or by scanning and sending by email to [redacted]

400 S.W. EIGHTH STREET, SUITE E • DES MOINES, IA 50309-4688
PHONE: 515-281-5944 • https://pharmacy.iowa.gov • FAX: 515-281-4609

BEFORE THE INDIANA BOARD OF PHARMACY
CAUSE NUMBER: 2019 IBP 0041

IN THE MATTER OF THE LICENSE OF:)
)
McKESSON DRUG COMPANY)
LICENSE NO: [redacted])

FILED
FEB 19 2020
Indiana Professional Licensing Agency

FINAL ORDER ACCEPTING PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

The State of Indiana ("Petitioner"), by counsel Timothy M. Weber, Deputy Attorney General, and McKesson Drug Company ("Respondent"), by counsel Randall Fearnow, signed a Proposed Settlement Agreement ("Agreement") which purports to resolve all issues involved in the action regarding Respondent's license before the Indiana Board of Pharmacy ("Board"), and which Agreement has been submitted to the Board for approval.

The Board, after reviewing the Agreement at the January 13, 2020 meeting held in Room W064 of the Indiana Government Center South, 402 West Washington Street, Indianapolis, Indiana, now finds it has been entered into fairly and without fraud, duress, or undue influence, and is fair and equitable between the parties. The Board hereby incorporates the Agreement which is attached hereto and incorporated herein as **Exhibit A** and approves and adopts in full the Agreement as a resolution of this matter. The Board approved this Agreement by a vote of 6-0-0. Incorporated into the Agreement was the consensus of both parties to Findings of Fact, Conclusions of Law, and Order.

WHEREFORE, the Board hereby accepts and approves the Agreement, settling all matters in this case consistent with the terms of the Agreement between the parties, and Respondent is hereby **ORDERED** to abide by all the terms of the Agreement as set forth below:

1. Respondent's license to practice as a wholesale drug distributor in the state of Indiana shall be placed on **INDEFINITE PROBATION**. As a term of this probation, and with the exception of the activities discussed in Paragraph 3 below, Respondent may not distribute controlled substances into Indiana effective as of the effective date of the Agreement until Respondent's DEA Registration is fully re-instated on or about February 16, 2021. In the event that Respondent's DEA Registration will remain suspended beyond February 16, 2021, Respondent shall notify the Board prior to the date of the continued suspension of its DEA Registration and the date that the suspension of its DEA Registration will terminate.

2. After the DEA Registration is fully re-instated, Respondent may submit a Petition to Withdraw the Probation to request that the probation be lifted.

3. The restriction of Respondent's ability to distribute controlled substances in the state of Indiana shall not apply to or limit Respondent's authority to distribute, or Respondent's operations involving, List 1 chemical products at or from Respondent which are authorized under Respondent's DEA Registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under Respondent's exclusive contract with the United States Department of Veteran Affairs.

4. Respondent shall fully comply with the 2017 Agreements and any amendments or modifications thereto, entered into by Respondent and the United States Department of Justice and Drug Enforcement Administration, and effective on January 17, 2017.

5. Within **NINETY (90) DAYS** of the final order in this matter, Respondent shall pay a **FINE** in the amount of **ONE THOUSAND DOLLARS ($1,000.00)**. This fine shall be paid by check or money order payable to the Indiana Professional Licensing Agency, and submitted to the following address:

Indiana Professional Licensing Agency
Attn: Board of Pharmacy
402 W. Washington Street, Room W072
Indianapolis, IN 46204

6. Within **NINETY (90) DAYS** of the final order in this matter, Respondent shall, pursuant to Ind. Code § 4-6-14-10(b), pay a **FEE** in the amount of **FIVE DOLLARS ($5.00)** to be deposited into the Health Records and Personal Identifying Information Protection Trust Fund. This fee shall be paid by check or money order payable to the State of Indiana, and submitted to the following address:

Office of the Indiana Attorney General
Attn: Executive Assistant, Consumer Protection Division
[redacted] West Washington Street, 5th Floor
Indianapolis, IN 46204

7. A violation of the Final Order, any non-compliance with the statutes or regulations regarding the practice of wholesale drug distribution, or any violation of this Agreement may result in Petitioner requesting a summary suspension of Respondent's license, an Order to Show Cause as may be issued by the Board, or a new cause of action pursuant to Ind. Code § 25-1-9-4, any or all of which could lead to additional sanctions, up to and including a revocation of Respondent's license.

SO ORDERED, this 19th day of February 2020.

INDIANA BOARD OF PHARMACY

By: Maureen Bennett
for Matt Balla, R. Ph., President

CERTIFICATE OF SERVICE

I certify that a copy of the "Final Order Accepting Proposed Findings of Fact, Conclusions of Law, and Order" has been duly served upon:

McKesson Drug Company
[redacted] Kenskill Ave
Washington Court House, OH 43160
Service by U.S. Mail

Randall Fearnow
QUARLES & BRADY, LLP
[redacted] LaSalle Street, Suite 4000
Chicago, Illinois 60654-3406
Service by U.S. Mail

Timothy M. Weber
OFFICE OF THE INDIANA ATTORNEY GENERAL
Indiana Government Center South, Fifth Floor
[redacted] Washington Street
Indianapolis, Indiana 46204-2770
Service by Email: timothy.weber@atg.in.gov

2-19-2020
Date

Nathaniel Black Jr., Litigation Specialist

Indiana Board of Pharmacy
Indiana Government Center South
402 West Washington St., Room W072
Indianapolis, IN 46204
Phone: 317-234-2067
Fax: 317-233-4236
Email: pla4@pla.in.gov

Explanation of Service Methods
Personal Service: by delivering a true copy of the aforesaid document(s) personally.
Service by U.S. Mail: by serving a true copy of the aforesaid document(s) by First Class U.S. Mail, postage prepaid.
Service by Email: by sending a true copy of the aforesaid document(s) to the individual's electronic mail address.

BEFORE THE INDIANA BOARD OF PHARMACY
CAUSE NO: 2019 IBP 0041

IN THE MATTER OF THE LICENSE OF:)
)
McKESSON DRUG COMPANY)
LICENSE NO: [redacted])

FILED
JAN 08 2020
Indiana Professional Licensing Agency

SETTLEMENT AGREEMENT

The State of Indiana ("Petitioner"), by Timothy M. Weber, Deputy Attorney General, and McKesson Drug Company ("Respondent"), by counsel, Randall Fearnow, hereby execute this Settlement Agreement ("Agreement") to resolve all issues raised by the filing of the Petitioner's Complaint in the above captioned matter and the Respondent's objections thereto. This Agreement is subject to the review and approval of the Indiana Board of Pharmacy ("Board") pursuant to Ind. Code § 25-1-9 and Ind. Code § 4-21.5-3.

STIPULATED FACTS

1. Respondent is a licensed wholesale drug distributor in the State of Indiana having been issued license number [redacted]

2. Respondent's address is 2000 Kenskill Ave., Washington Court House, Ohio 43160.

3. Respondent is one of several wholesale distribution centers operated by its parent company, McKesson Corporation (parent company hereinafter referred to as "McKesson").

4. On January 17, 2017, McKesson entered into a Settlement Agreement and Release and an Administrative Memorandum of Agreement (collectively, the "2017 Agreement") with the Drug Enforcement Agency ("DEA") and the Department of Justice ("DOJ"). Pursuant to the terms of the 2017 Agreement, the parties agreed in relevant part.

EXHIBIT A

a. At times relevant to the 2017 Agreement, McKesson's distribution centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* ("CSA"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

b. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation.

c. In 2006 and 2007, the DEA sent letters to every entity in the United States that was registered with the DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The letters contained guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b).

d. In 2008, McKesson entered into a settlement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to as the "2008 Agreements").

e. The 2017 Agreement covers the time period of January 1, 2009 through the date of the last signatory to the 2017 Agreement, which was on January 17, 2017 ("Covered Time Period").

5. Pursuant to the 2017 Agreement, Respondent's DEA Certificate of Registration ("DEA Registration") will be suspended between February 16, 2019 and February 16, 2021 with a partial exception to possess and distribute controlled substances related to servicing federal customers that purchase from Respondent under an exclusive contract with the United States Department of Veterans

Affairs. The suspension does not apply to or limit McKesson's authority to distribute, or operations involving List 1 Chemical products.

6. Indiana Code § 25-1-9-4(a)(3) allows the Board to discipline a practitioner if the Board finds that the practitioner has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question.

7. Indiana Code § 25-26-14-17(10) requires a wholesale distributor, if involved in the distribution of controlled substances, to maintain registration with the federal Drug Enforcement Agency.

STIPULATED CONCLUSION OF LAW

The parties further stipulate Respondent's Indiana license is subject to discipline in accordance with Indiana Code § 25-1-9-4(a)(3) because Respondent's DEA Registration was suspended; therefore, it did not maintain registration with the DEA as required by Indiana Code § 25-26-14-17(10).

AGREED DISPOSITION

It is now therefore agreed by Respondent and Petitioner as follows:

1. Both parties voluntarily waive their rights to a public hearing on the Complaint and all other proceedings in this action to which either party may be entitled by law, including judicial review and appeal.

2. This Agreement resolves any and all pending claims or allegations relating to disciplinary action against the Respondent's Indiana wholesale drug distributor license.

3. Respondent's license to practice as a wholesale drug distributor in the state of Indiana is hereby placed on INDEFINITE PROBATION. As a term of this probation, and with the exception of the activities discussed in Paragraph 5 below, Respondent may not distribute controlled substances into Indiana effective as of the effective date of this Agreement until Respondent's DEA Registration is fully

re-instated on or about February 16, 2021. In the event that Respondent's DEA Registration will remain suspended beyond February 16, 2021, Respondent shall notify the Board prior to the date of the continued suspension of its DEA Registration and the date that the suspension of its DEA Registration will terminate.

4. After the DEA Registration is fully re-instated, Respondent may submit a Petition to Withdraw the Probation to request that the probation be lifted.

5. The restriction of Respondent's ability to distribute controlled substances in the state of Indiana shall not apply to or limit Respondent's authority to distribute, or Respondent's operations involving, List I chemical products at or from Respondent which are authorized under Respondent's DEA Registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the United States Department of Veterans Affairs.

6. Respondent shall fully comply with the 2017 Agreement and any amendments or modifications thereto, entered into by Respondent and the United States Department of Justice, Drug Enforcement Administration and effective on January 17, 2017.

7. Within ninety (90) days of the Board's Final Order accepting this Agreement, Respondent shall pay a **FINE** in the amount of **ONE THOUSAND DOLLARS ($1,000.00).** This fine shall be paid by check or money order payable to the Indiana Professional Licensing Agency, and submitted to the following address:

Indiana Professional Licensing Agency
Attn: Board of Pharmacy
402 W. Washington Street, Room W072
Indianapolis, Indiana 46204

8. Within **NINETY (90) DAYS** of the Final Order, Respondent shall, pursuant to Ind. Code § 4-6-14-10(b), pay a **FEE** in the amount of **FIVE DOLLARS ($5.00)** to be deposited into the Health Records and Personal Identifying Information Protection Trust Fund. This fee shall be paid by check or money order payable to the State of Indiana, and submitted to the following address:

Office of the Indiana Attorney General
Attn: Teresa Henson
[redacted] West Washington Street, 5th Floor
Indianapolis, IN 46204

9. Respondent has carefully read and examined this Agreement and fully understands its terms and that, subject to approval by the Board, this Agreement is a final disposition of the Allegations.

10. The hearing set in this matter shall be vacated upon approval of the Board.

IN WITNESS WHEREOF, the undersigned, authorized representatives of the parties, affix their signatures hereto evidencing their acceptance of this Agreement.

Annie McKay — 1-6-2020
Representative for Respondent — Date

1-7-2020
Randall R. Fearnow — Date
Counsel for Respondent

1-7-2020
Timothy M. Weber — Date
Deputy Attorney General

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION OF THE ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION,	Complainant,	) Case No. [redacted]
v.		
MCKESSON CORPORATION, License No. [redacted] License No. License No.	Respondent.	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by attorney Brandon R. Thom, and Respondent McKesson Corporation ("Respondent"), by attorney Roger N. Morris of Quarles & Brady LLP, agree to the following:

STIPULATIONS

Respondent holds multiple Wholesale Drug Distributor licenses in the State of Illinois, including license numbers 004.002044 (Aurora, Colorado), 004.001511 (Livonia, Michigan), and 004.000755 (Washington Court House, Ohio). On January 17, 2017, Respondent entered into a Settlement Agreement and Administrative Memorandum of Agreement with the U.S. Department of Justice-Drug Enforcement Administration ("DEA"). The January 17, 2017 Memorandum of Agreement is attached herein as **Exhibit 1.** The DEA alleged various conduct which the DEA alleged would constitute violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et sequ (the "Act") and regulations promulgated under the Act at 21 C.F.R. Part 1300 *et seq.* To resolve the matter, Respondent made no admissions of liability but agreed to pay a settlement payment of one hundred fifty million dollars ($150,000,000) and agreed to a time-limited suspension of the DEA Certification of Registrations of four (4) of Respondent's distribution centers, including those listed herein. Respondent's actions and/or omissions, if proven true, would constitute violations of the Illinois Wholesale Drug Distribution Licensing Act, 225 ILCS 120/55(a)(1) and (5).

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and parties herein. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the Department or any person and has not relied upon any representation made by or on behalf of the Department other than those specifically included

herein. Respondent has been advised of the right to accept or reject this Consent Order. Respondent has been advised of the right to a hearing on the Petition for Restoration, the right to contest any charges brought, and the right to administrative review of any Order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Board of Pharmacy ("Board") or Director. Respondent acknowledges that the Department attorney may be requested to communicate with the Board or Director in furtherance of the approval of this Consent Order. Respondent has been informed that this Consent Order will be presented to the Director for final approval. If this Consent Order is not approved, Respondent waives any right to raise any prejudice resulting from the Director's consideration of this Consent Order. Respondent understands that this Consent Order is not effective unless and until it is adopted by the Director. A copy of any original signature(s) shall be given the full force and effect of any original signature(s) affixed to this Consent Order.

Respondent and the Department have agreed, in order to resolve this matter, that Respondent be permitted to enter into a Consent Order with the Department.

CONDITIONS

Wherefore, the Department, by attorney Brandon R. Thom, and Respondent, by attorney Roger N. Morris of Quarles & Brady LLP, agree:

A. Respondent's Illinois Wholesale Drug Distributor license no. [redacted] (Aurora, Colorado), shall be placed on probation for a definite period of three (3) years, effective January 17, 2017 to January 17, 2020. Throughout the term of this probation, Respondent's Illinois Wholesale Drug Distributor license no. [redacted] (Aurora, Colorado) shall be prohibited from distributing controlled substances in the State of Illinois. This probationary restriction shall not apply to or limit Respondent's authority to distribute, or operations involving, List 1 Chemical products at or from Respondent's Aurora, Colorado distribution center.

B. Respondent's Illinois Wholesale Drug Distributor license no. [redacted] (Livonia, Michigan), shall be placed on probation for a definite period of two (2) years, effective January 17, 2017 to January 17, 2019.

Throughout the term of this probation, Respondent's Illinois Wholesale Drug Distributor license no [redacted] (Livonia, Michigan) shall be prohibited from distributing controlled substances in the State of Illinois. This probationary restriction shall not apply to or limit Respondent's authority to distribute, or operations involving, List I Chemical products at or from Respondent's Livonia, Michigan distribution center. Respondent's Livonia, Michigan distribution center is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the U.S. Department of Veterans Affairs.

C. Respondent's Illinois Wholesale Drug Distributor license no. ([redacted] (Washington Court House, Ohio), shall be placed on probation for a definite period of two (2) years, effective February 16, 2019 to February 16, 2021. Throughout the term of this probation, Respondent's Illinois Wholesale Drug Distributor license no. [redacted] (Washington Court House, Ohio) shall be prohibited from distributing controlled substances in the State of Illinois. This probationary restriction shall not apply to or limit Respondent's authority to distribute, or operations involving, List I Chemical products at or from Respondent's Washington Court House, Ohio distribution center. Respondent's Washington Court House, Ohio distribution center is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the U.S. Department of Veterans Affairs.

D. Respondent shall comply with all terms and conditions imposed upon Respondent in the January 17, 2017 DEA Memorandum of Agreement, attached hereto as Exhibit 1. Any violation of the Memorandum of Agreement by Respondent shall be deemed a violation of this Consent Order.

E. Respondent shall comply with all terms and conditions of the Wholesale Drug Distribution Licensing Act 225 ILCS 120/1 et seq. and the Rules enacted in furtherance thereof. Respondent's failure to do so shall be deemed a violation of the terms of this Consent Order.

F. Failure by Respondent to comply fully with the terms and conditions of this Consent Order may be grounds for the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation to issue an Order mandating the immediate and automatic indefinite suspension of Respondent's Illinois Wholesale Drug Distributor Licenses, numbers [redacted] Respondent may file an appropriate Petition within thirty (30) days from date the order was entered to contest the

underlying factual basis of the indefinite suspension. Respondent shall be afforded a hearing on the merits following the filing of the Petition. Respondent waives any statute of limitations defense in any hearing on the indefinite suspension.

G. This Consent Order is a public disciplinary action and will be reported to all applicable public indexes. This Consent Order will be available to the general public.

H. This Consent Order shall become effective upon the Director's approval and signature, as dated below.

April 21, 2021
Date

Department Attorney Brandon R. Thom

April 12, 2021
Date

Respondent McKesson Corporation

April 12, 2021
Date

Roger N. Morris of Quarles & Brady LLP
Attorney for Respondent

4/20/21
Date

Illinois Board of Pharmacy Member

The foregoing Consent Order is approved in full.

Dated this 22nd day of May, 2021.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
ACTING SECRETARY MARIO TRETO, JR.

Acting Director Cecilia Abundis
Division of Professional Regulation

Case No.
License Nos. [redacted]

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425.

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration [redacted] located at [redacted] Kenskill Avenue, Washington Court House, Ohio [redacted] McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration [redacted] located at [redacted] Plymouth Road, Livonia, Michigan [redacted] McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration [redacted] located at [redacted] Kendrick Lane, Lakeland, Florida [redacted] McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration [redacted] located at [redacted] Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration [redacted] located at [redacted] McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration [redacted] located at [redacted] Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration [redacted] located at [redacted] Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at [redacted] South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration [redacted] located at [redacted] McKesson Drive, Ruther Glen, Virginia [redacted] and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration [redacted] located at [redacted] Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f. The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1 Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number [redacted]

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration numbe[redacted] McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, [redacted]oward Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration [redacted], for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number [redacted] McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA. Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, [redacted] Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration [redacted] for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration [redacted] will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, [redacted] North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration [redacted], for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, *e.g.*, administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration [redacted] and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration [redacted], and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration [redacted] to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or

e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, [redacted] Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, [redacted] Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, [redacted] (2 Constitution Square), [redacted] East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post [redacted]
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
[redacted] State Highway 161
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post S[redacted]
San Francisco, CA 94104

7. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8. Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9 Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

By J. Louis Milione for

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

May 27, 2021

Sent via email: [redacted]

McKesson Corporation
Michele Lau, VP/Secretary/Director
1 Post Street
San Francisco, CA[redacted]

Re: Complaint No. [redacted]

Dear Ms. Lau:

Enclosed please find the fully executed consent agreement between you, the Maine Board of Pharmacy, and the Office of the Attorney General in the above referenced matter.

This letter also acknowledges receipt of your fine payment in the amount of $500.00. Your fine is paid in full. As all conditions of the consent agreement have been fulfilled, this complaint file is now closed.

Please feel free to contact our office at [redacted] with any questions.

Sincerely,

Jessica Gowell

Jessica Gowell, Professional Licensing Supervisor

Enclosure

cc: John Nichols, Esq., Assistant Attorney General
Andrew Black, Esq., Assistant Attorney General
Geraldine L. Betts, Board Administrator & Complainant
Thomas Avery, Board Investigator

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MCKESSON CORPORATION	)	CONSENT AGREEMENT
	)	
Case No. [redacted]	)	

PARTIES

This document is a Consent Agreement regarding the pending application of McKesson Corporation for the renewal of its prescription drug wholesaler license. The parties to this Consent Agreement are: McKesson Corporation ("McKesson"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since October 17, 2011, McKesson has been licensed in Maine as a prescription drug wholesaler with a registered location of 1995 McKesson Street, Suite 101, Aurora, Illinois (license numbe[redacted]

2. On October 4, 2019, the Colorado State Board of Pharmacy imposed discipline against McKesson's Colorado registration as an out-of-state prescription drug wholesaler (Registration # [redacted]n Case No. [redacted]

3. McKesson then failed to report the Colorado disciplinary action to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On November 22, 2019, McKesson submitted an application for renewal of its Maine license and reported to the Board for the first time that it had been disciplined by the Colorado State Board of Pharmacy.

5. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

6. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny McKesson's application for renewal of its license to be a prescription drug wholesaler. In lieu of the denial, the Board also voted to offer McKesson this Consent Agreement. Unless McKesson either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, by **May 16, 2021,** the preliminary denial of McKesson's application for licensure as a prescription drug wholesaler will become final.

COVENANTS

7. McKesson admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken in another jurisdiction against a professional license no later than 10 days after the action was taken.

8. As discipline for the violation admitted to in paragraph 7 above, McKesson agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of five hundred dollars ($500.00) payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

9. Upon receipt of the signed Consent Agreement with the enclosed payment of the civil penalty from McKesson, the Board will renew McKesson's license contingent upon it meeting all other eligibility criteria.

10. Violation of any of the terms or conditions of this Consent Agreement by McKesson shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. The Board and McKesson agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless McKesson fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against McKesson, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving McKesson. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against McKesson.

12. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

13. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. McKesson acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: May 5, 2021

MCKESSON CORPORATION

By: _____

Print Name: Michele Lau

Title: Senior VP & Corporate Secretary

DATED: 5/26/21

_____

BRADLEY S. HAMILTON, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 5/27/21

_____

JOHN NICHOLS
Assistant Attorney General

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. [redacted]

McKesson Corporation
c/o Todd Spaulding
3000 Kenskill Avenue
Washington Court House, Ohio 43160

License N [redacted]

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Corporation, for the purpose of resolving all issues between the parties relating to the Board investigation of McKesson's Settlement Agreement with the Drug Enforcement Administration (DEA) and their alleged failure to report suspicious orders to the Board. Together, the Board and McKesson Corporation are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. McKesson Corporation, is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-0977250, which lists Todd Spaulding, as the Responsible Person.

FACTS

1. The Board initiated an investigation of McKesson Corporation, Wholesaler Distributor of Dangerous Drugs License No. 01-0977250, related to McKesson Corporation's Settlement Agreement with the Drug Enforcement Administration (DEA) and their alleged failure to report suspicious orders to the Board.

2. On or about February 10, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson Corporation, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

3. On or about February 24, 2021, McKesson Corporation, through counsel, timely requested an administrative hearing, which was subsequently scheduled for August 9, 2021.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson denies the allegations stated in the Notice of Opportunity for Hearing letter dated February 10, 2021 and contests all allegations pertaining to suspicious order reporting; however, the Board maintains that it has evidence sufficient to sustain the allegations, such that if proven at hearing would constitute a finding that McKesson violated Ohio's pharmacy law(s) as set forth in the Notice of Opportunity for Hearing, and hereby adjudicates the same.

3. McKesson Corporation agrees to pay to the Board a monetary penalty in the amount of $20,000.00. This fine will be attached to your license record and must be paid no later than 60 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson Corporation's WDDD License [redacted] will be reprimanded, effective the date of this Agreement.

5. McKesson Corporation agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. McKesson Corporation agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson Corporation of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson Corporation by the Board and will NOT discharge McKesson Corporation from any obligation under the terms of this Agreement.

7. McKesson Corporation agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. McKesson Corporation understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson Corporation will operate.

10. McKesson Corporation explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Ammie McAsey, Senior Vice President - Customer Distribution Experience, on behalf of, McKesson Corporation, Respondent — Date of Signature: 10/12/2021

Roger N. Morris, Attorney for Respondent — Date of Signature: 10/1/2021

Rich Miller, RPh, President, State of Ohio Board of Pharmacy — Date of Signature: 10/14/2021

Henry Appel, Ohio Assistant Attorney General — Date of Signature: 10/14/2021

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION OF THE ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION, Complainant,	)	
v.	)	[redacted]
MCKESSON CORPORATION D/B/A MCKESSON DRUG COMPANY, License No. 004.004206. Respondent	)	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by Chief of Health-Related Prosecutions Mary C. Meehan, and Respondent McKesson Corporation d/b/a McKesson Drug Company ("Respondent") through its attorney Alex Cooper of Quarles & Brady, LLP, agree to the following:

STIPULATIONS

Respondent holds Illinois licensed wholesale drug distributor license no. 004.004206, which is currently in active status. On or about January 7, 2020, the Iowa Board of Pharmacy disciplined Respondent based on allegations that Respondent failed to take a full inventory of products in violation of 657 Iowa Administrative Code 10.19. The grounds cited by the Iowa Board of Pharmacy are substantially similar to the 77 Illinois Administrative Code 1510.120(f). Respondent's actions and/or omissions are grounds for discipline under the Pharmacy Practice Act ("Act") at 225 ILCS 120/55(a)(5). Respondent neither admits nor denies the allegations but Respondent acknowledges that should this matter proceed to a contested hearing, the Illinois State Board of Pharmacy ("Board") could find a violation of the Illinois Wholesale Drug Distributor Act. The Department and Respondent stipulate that the above acknowledgement is made only for the purposes of this Consent Order. In the event that this Consent Order is not approved by the Board or the Director of the Division of Professional Regulation of the Department ("Director"), this acknowledgement shall not be admissible in any proceeding and the matter will be set for an evidentiary hearing on the merits as if this Consent Order had not been submitted.

At all times material to the matter set forth in this Order, the Department had jurisdiction over the subject matter and the parties herein. Respondent has been advised of the right to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, the right to contest the pending charges and present mitigating evidence, and the right to administrative review of any order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Board or Director. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the Department or any person, and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Respondent acknowledges that the Department attorney may be requested to communicate with the Board or Director in furtherance of the approval of this Consent Order. Respondent acknowledges this Consent Order will be presented to the Director. If this Consent Order is not approved, Respondent waives any right to raise any prejudice resulting from the Director's consideration of this Consent Order. Respondent understands that this Consent Order is not effective unless and until it is adopted by the Director. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Respondent and the Department agree in order to resolve this case that Respondent be permitted to enter into a Consent Order with the Department, providing for the terms and conditions contained herein which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by Chief of Health-Related Prosecutions Mary C. Meehan, and Respondent, by its attorney Alex Cooper of Quarles & Brady, LLP agree:

A. Respondent's Illinois licensed wholesale drug distributor license no. 004.004206 shall be reprimanded.

B. This Consent Order is a public disciplinary action and will be reported to all applicable public indexes.

C. This Consent Order shall become effective upon the signature of the Director, as dated below.

11/15/2021 — Chief of Health-Related Prosecutions Mary C. Meehan
Date

10.12.2021 — Ammie McAsey, SVP, Customer Distribution Experience, McKesson PSAS
Date
Representative for Respondent McKesson Corporation d/b/a McKesson Drug Company

10/12/21 — Respondent Attorney Alex Cumpata of Quarles & Brady, LLP
Date

11/8/21 — Illinois State Board of Pharmacy Member
Date

This Consent Order is approved in full.

Dated this 20th day of December, 2021

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
ACTING SECRETARY MARIO TRETO JR.

Acting Director Cecilia Abundis
Division of Professional Regulation

Case No 2020-00770
License No. 004 004206

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 22, 2022

CERTIFIED MAIL

McKesson Drug Company
Attn: Sandra Zamora
[redacted]Norwalk
Santa Fe Springs, CA 90670

RE: Administrative Case No. [redacted]
McKesson Corporation dba McKesson Drug Company, WLS 3076

Dear Ms. Zamora:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to page 4 of the document.

Effective at 5:00 p.m. on March 24, 2022, Wholesale Permit No. [redacted] issued to McKesson Drug Company shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at [redacted] Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Christina Thomas, DAG
Amy Levine Heiserman, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. [redacted]
McKesson Drug Company, WLS 3076

I am over 18 years of age, and not a party to the within cause; my business address is [redacted] Gateway Oaks Drive, [redacted] Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
McKesson Drug Company Attn: Sandra Zamora [redacted] Norwalk Santa Fe Springs, CA 90670	7017 0190 0000 4212 5618
Amy Levine Heiserman, Esq. Quarles & Brady LLP One Renaissance Square [redacted] Avenue, Suite 600 Phoenix, AZ 85004-2322	7017 0190 0000 4212 5625

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 22, 2022, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 22, 2022 at Sacramento, California.

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against:

MCKESSON CORPORATION, dba
MCKESSON DRUG COMPANY,
Wholesale Permit No. [redacted]

and

JOHN F. BOHLINGER,
Designated Representative License No. EXC [redacted]

Respondents

Agency Case No. [redacted]

OAH No. [redacted]

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 24, 2022.

It is so ORDERED on February 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **[redacted] Norwalk Boulevard** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **[redacted] Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. [redacted] OAH No. [redacted] **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL (AS TO MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY, ONLY)** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Christina Thomas, Deputy Attorney General.

2. Respondent McKesson Corporation, dba McKesson Drug Company (Respondent) is represented in this proceeding by attorney Alissa Brice Castenada, whose address is: Quarles & Brady LLP One Renaissance Square Two North Central Avenue Phoenix, AZ 85004-2391

JURISDICTION

3. On or about October 2, 1995, the Board issued Wholesale Permit No. [redacted] to McKesson Corporation, dba McKesson Drug Company. The Wholesale Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 6850 and will expire on October 1, 2022, unless renewed.

4. First Amended Accusation No. 6850 was filed before the Board of Pharmacy, Department of Consumer Affairs and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on January 4, 2021. Respondent timely filed its Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 6850 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 6850. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent denies the allegations in First Amended Accusation No. 6850.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

10. Respondent agrees that its Wholesale Permit is subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,

supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Wholesale Permit No. WLS 3076 issued to Respondent McKesson Corporation, dba McKesson Drug Company, shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6850, attached as exhibit A.

Cost Recovery. No later than 60 days from the effective date of the Decision, Respondent shall pay $147,780.00 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew its Wholesale Permit Number until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in First Amended Accusation No. 6850, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Wholesale Permit No. WLS 3076.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Alissa Brice Castaneda. I understand the stipulation and the effect it will have on my Wholesale Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

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DATED: 12/17/2021

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 12/17/2021

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 12/17/21

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 6850

XAVIER BECERRA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
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300 So. Spring Street, Suite 1702
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **[redacted]S. Norwalk** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **[redacted]Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. [redacted] **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about October 2, 1995, the Board of Pharmacy issued Wholesale Permit Number [redacted]o McKesson Corporation, dba McKesson Drug Company (Respondent

McKesson). The Wholesale Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2021, unless renewed.

3. On or about January 21, 2004, the Board of Pharmacy issued Original Certificate Number EXC 17318 to John F. Bohlinger (Respondent Bohlinger) to act as a Designated Representative. The certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2021, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 4300 of the Code states:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

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8. California Health and Safety Code section 11153.5 states, in pertinent part:

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes."

...

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

9. Section 4169.1 of the Code (effective January 1, 2018), states:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

10. Section 4059.5, subsection (a), of the Code states:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

REGULATORY PROVISIONS

11. Code of Federal Regulations, title 21, section 1301.74, subsection (b), states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

12. California Code of Regulations, title 16, section 1783, states, in pertinent part:

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

COST RECOVERY

13. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

14. Section 4021 of the Code states: "'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

15. Section 4022 of the Code states: "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.

...

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

16. Phenergan with Codeine Syrup 6.25 mg – 10 mg / 5 ml is the brand name for promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C), a Schedule V controlled substance designated by California Health and Safety Code section 11058(c)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat coughing.

17. Xanax is the brand name for alprazolam, a Schedule IV controlled substance designated by California Health and Safety Code section 11057(d)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat anxiety.

FACTUAL ALLEGATIONS – CHILDREN'S MEDICAL CENTER PHARMACY

18. At all times relevant herein, the Children's Medical Center Pharmacy, also known as the Rady Children's Outpatient Pharmacy (Rady Pharmacy), was part of the Rady Children's Hospital of San Diego. According to its website, it is the only hospital in the San Diego area dedicated exclusively to pediatric healthcare.

19. Between May 7, 2017 and June 26, 2018, the Rady Pharmacy could not account for an inventory shortage of approximately 119 pints of P/C and 5,300 tablets of alprazolam 2mg. A pharmacy technician at the Rady Pharmacy had stolen these dangerous drugs and controlled substances for herself and her friends.

Promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C)

20. Based on Lexicomp Online, a collection of clinical database and clinical decision support tools, P/C is not recommended in pediatrics due to risk of adverse effects, such as slowed or difficult breathing, misuse, abuse, addiction, overdose, and death.

21. According to the pharmacy manager, the Rady Pharmacy did not use or dispense P/C because pediatric doctors did not prescribe P/C to children. On the rare occasion the doctor prescribed P/C, it would be during the winter season according to the pharmacy manager.

22. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, less than two 16-ounce bottles of P/C **per year** to the Rady Pharmacy between January 2014 and August 2017. Beginning in September 2017, the sales of P/C displayed an irregular pattern compared to the previous ordering pattern:

P/C Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (16oz) of P/C Sold**
September 2017	11
October 2017	7
November 2017	7
December 2017	10
January 2018	14
February 2018	10
March 2018	15
April 2018	10
May 2018	18
June 2018	17

23. When calculating the monthly percentage change in sales, there were sales of P/C which varied from 40% to 80% more than the sale from the previous month.

24. The orders for P/C beginning in September 2017 were significantly larger and were shipped in consecutive months from September 2017 to June 2018, which totaled approximately 119 pints or 56,287 ml of P/C.

Alprazolam 2mg

25. Alprazolam is available in dosages of 0.25 mg, 0.5 mg, 1 mg, and 2mg.

26. According to Lexicomp Online, alprazolam should be titrated and used at the lowest effective dose. Lexicomp provided the following dosing information: "*Children ≥ 7 years and Adolescents < 18 years: Limited data available... Initial: 0.005 to 0.02 mg/kg/dose 3 times daily... maximum of 0.02 mg/kg/dose.*" For example, if a child is 40 kg (about 88 pounds), the dosing range is from 0.2 to 0.8 mg per dose.

27. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, one bottle of 100-count alprazolam 2mg **per year** between January 2014 and September 2017. Beginning in October 2017, the sales of alprazolam 2mg displayed an irregular pattern compared to the previous ordering pattern:

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Alprazolam 2mg Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (100-count) of alprazolam 2mg Sold**
October 2017	7
November 2017	9
December 2017	8
January 2018	4
February 2018	4
March 2018	4
April 2018	0
May 2018	15

28. When calculating the monthly percentage change in sales, there were sales of alprazolam 2mg which varied from 250% to 275% more than the sale from the previous month.

29. The orders for alprazolam 2mg beginning in October 2017 were significantly larger and were shipped in consecutive months (except April 2018) from October 2017 to May 2018, which totaled approximately 5,100 tablets of alprazolam 2 mg.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Excessive Furnishing of Controlled Substances)

30. Respondents are subject to disciplinary action under Code section 4301, subsection (e), in that Respondents clearly and excessively furnished controlled substances in violation of California Health and Safety Code section 11153.5, subsection (a), as follows:

a. Respondents furnished the Rady Pharmacy one to two pints of P/C in non-consecutive months from January 2014 to August 2017. Sales increased to seven to 18 pints ordered in consecutive months from September 2017 to June 2018.

b. Respondents furnished the Rady Pharmacy 100 to 200 tablets of alprazolam 2mg in non-consecutive months from January 2014 to September 2017. Sales increased to 400 to 1,500 tablets ordered in consecutive months from October 2017 to May 2018 (except April 2018).

c. Respondents furnished the Rady Pharmacy large quantities of controlled substances (P/C and alprazolam 2mg) that are not typically distributed to pediatric patients.

d. The P/C and alprazolam 2mg furnished by Respondents were not dispensed to patients for legitimate medical purposes but were diverted by a pharmacy technician.

Paragraphs 18 to 29 are re-alleged as if fully set forth herein.

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FACTUAL ALLEGATIONS – CARING PHARMACY

31. On January 7, 2020, a Board inspector conducted an inspection of Caring Pharmacy (Caring Pharmacy), located at [redacted] Hemingway Avenue #103, Stevenson Ranch, CA 91381. K.F. is a licensed pharmacist and the owner of Caring Pharmacy. S.F. is K.F's wife and is an unlicensed individual.

32. During this inspection at approximately 9:30 a.m., the Board inspector observed Respondent McKesson's delivery driver bring a drug tote (Drug Tote) to S.F.'s car in front of Caring Pharmacy. S.F. signed for the delivery, and the delivery driver left. S.F. subsequently brought the Drug Tote into Caring Pharmacy.

33. Shortly thereafter, the Board inspector entered Caring Pharmacy, and S.F. stated that no pharmacist was present at Caring Pharmacy at that time. The invoice that accompanied the Drug Tote revealed that the Drug Tote consisted of Emgality and Repatha, both of which are dangerous drugs under California Business and Professions Code section 4022.

SECOND CAUSE FOR DISCIPLINE

(Violation of Statute Regulating Dangerous Drugs)

34. Respondents are subject to disciplinary action under Code section 4301, subsection (j), in that Respondents committed unprofessional conduct by violating California Business and Professions Code section 4059.5, subsection (a). Specifically, on or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for or received by a pharmacist. The drugs were signed for by an unlicensed individual.

THIRD CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law)

35. Respondents are subject to disciplinary action under Code section 4301, subsection (o), in that Respondents committed unprofessional conduct by violating the following Pharmacy Law and regulations:

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a. California Business and Professions Code section 4059.5, subsection (a): On or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for and received by a pharmacist. The drugs were signed for by an unlicensed individual.

b. California Code of Regulations, title 16, section 1783: On or about January 7, 2020, Respondents delivered dangerous drugs to an unlicensed person at Caring Pharmacy who was not an "authorized person" under California Code of Regulations, title 16, section 1783, subsection (b).

DISCIPLINARY CONSIDERATIONS

36. On April 5, 2018, the Board issued Citation No. CI 2014 63111 to Respondent McKesson for violating California Health and Safety Code section 11153.5 [wholesaler furnishing controlled substance other than for legitimate medical purposes] and assessed a fine of $5,000.00. Respondent McKesson has paid the fine.

37. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

38. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

39. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

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40. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Wholesale Permit Number WLS 3076 issued to McKesson Corporation, McKesson Corporation shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Wholesale Permit Number WLS 3076, issued to McKesson Corporation, dba McKesson Drug Company;

2. Revoking or suspending Designated Representative Number EXC 17318, issued to John F. Bohlinger;

3. Prohibiting McKesson Corporation from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if Wholesale Permit Number WLS 3076 issued to McKesson Corporation is revoked;

4. Ordering McKesson Corporation and John F. Bohlinger to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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5. Taking such other and further action as deemed necessary and proper.

DATED: 11/16/2020

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2020.11.16 05:53:42 -08'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

LA2019505103
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COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. [redacted] A consolidated with [redacted] A

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("the Board") and **RXC ACQUISITION COMPANY DBA RXCROSSROADS BY MCKESSON** ("Respondent"), and both having been fully informed regarding the matter set forth herein hereby agree to the entry of this **Agreed Order** to obviate a formal hearing.

Stipulations of Fact

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacies and pharmacists.

(2) Respondent is licensed as a pharmacy and was issued permit #[redacted]

(3) The Board alleges Respondent engaged in unprofessional or unethical conduct by failing to deliver medication to a patient in a timely manner.

(4) Staff at Respondent confirmed medication delivery dates on three separate occasions and the medication was not delivered to the patient on any of those specified dates. Due to unprecedented and unexpected call and prescription volumes during the relevant time period, patient spent several hours on hold with Respondent regarding the status of the medication and received the medication four (4) days after the first promised delivery date.

(5) The Board further alleges Respondent engaged in unprofessional or unethical conduct by failing to have a functioning auto-refill scheduling program for a period of eight (8) days. When Respondent learned of the failure in the technology, it promptly fixed the issue and the auto-refill scheduling program has been running correctly since that time. Because of the brief lapse in the auto-refill program, a patient enrolled in the program was not contacted to schedule a delivery before running out of medication.

(6) During the relevant time period, Respondent experienced a dramatic and unexpected increase in the number of incoming calls to the pharmacy due to forces outside Respondent's control.

Respondent went to great lengths to quickly hire and train staff members to handle the increased call volume. Nevertheless, Respondent was unable to respond to all patient and provider calls in a timely manner, and, in the most extreme examples, some callers were on hold for several hours before speaking to pharmacy staff.

Stipulated Conclusions of Law

(7) Respondent's license to operate a pharmacy in the Commonwealth is subject to regulation and discipline by the Kentucky Board of Pharmacy.

(8) Based upon the above allegations, the Board may discipline Respondent pursuant to KRS 315.121(1)(a).

(9) In lieu of the filing of a formal Complaint and hearing, the Board and Respondent have agreed to address this matter by entering into this Agreed Order.

Order

(1) Respondent is fined $5,000.00. The fine is payable on or before December 15, 2021. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, KY 40601.

(2) Respondent acknowledges that they have read and understand the terms of this Agreed Order and are entering into it freely, willingly, and voluntarily. Respondent further acknowledges that by entering into this Agreed Order, Respondent is freely, voluntarily, and willingly waiving all the due process rights afforded under the U. S. and Kentucky Constitutions, KRS Chapter 315 and the accompanying regulations in regard to disciplinary actions.

(3) By entering this Agreed Order, Respondent consents to the continuing jurisdiction of the Board and by signing, submits to that jurisdiction.

(4) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP") and is subject to disclosure under the Kentucky Open Records Act.

JILL RHODES
President
Kentucky Board of Pharmacy

12/6/2021
DATE

DocuSigned by:
Van Anderson
D1FA0F1A55D64CB...

VAN ANDERSON
Chief Counsel
McKesson Corporation
On Behalf of
RXC ACQUISITION COMPANY
DBA RXCROSSROADS BY MCKESSON
Respondent

11/14/2021
DATE

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION

2022 APR 14 P 1:33

DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

IVY Y. E. KIM 9609
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
[redacted] South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: (808) 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

DEPT. OF COMMERCE
AND CONSUMER AFFAIRS

eFiled 5/25/2022 8:57 am

HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of RXC ACQUISITION COMPANY, doing business as RXCROSSROADS BY MCKESSON, Respondent.	PHA[redacted] SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s) and Respondent RXC ACQUISITION COMPANY, doing business as RXCROSSROADS BY MCKESSON (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below:

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted as a miscellaneous permit holder by the Board of Pharmacy (hereinafter the "Board") under miscellaneous permit number PMP 1640. The miscellaneous permit was issued on or about July 30, 2019. The miscellaneous permit is set to expire or forfeit on or about December 31, 2023.

2. Respondent's mailing address for purposes of this action is 5101 Jeff Commerce Drive, Suite A, Louisville, Kentucky 40219.

I HEREBY CERTIFY THAT THE ATTACHED
IS A TRUE AND CORRECT COPY OF THE
ORIGINAL ON FILE IN THE DEPARTMENT
OF COMMERCE & CONSUMER AFFAIRS.

8. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's miscellaneous permit.

9. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

10. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. [redacted]

11. Respondent acknowledges that upon its approval, this Settlement Agreement constitutes disciplinary action and understands that this Settlement Agreement may be subject to reporting requirements.

12. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of FIVE HUNDRED AND NO/100 DOLLARS ($500.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: IVY Y. E. KIM, Esq., [redacted] Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1. above, Respondent's miscellaneous permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new miscellaneous permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new miscellaneous permit pursuant to and subject to HRS [redacted], and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Louisville (City), Kentucky (State), April 5, 2022 (Date)

RXC ACQUISITION COMPANY, doing business as RXCROSSROADS BY MCKESSON
Respondent

By: _____ (Signature)

Julie Anderson (Print Name)

Its Pharmacist-in-Charge (Print Title)

DATED: Honolulu, Hawaii, April 13, 2022

_____
IVY Y. E. KIM
Attorney for Department of Commerce and Consumer Affairs

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 20-0116 A consolidated with 20-0127 A

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("the Board") and **RXC ACQUISITION COMPANY DBA RXCROSSROADS BY MCKESSON** ("Respondent"), and both having been fully informed regarding the matter set forth herein hereby agree to the entry of this **Agreed Order** to obviate a formal hearing.

Stipulations of Fact

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacies and pharmacists.

(2) Respondent is licensed as a pharmacy and was issued permit #[redacted]

(3) The Board alleges Respondent engaged in unprofessional or unethical conduct by failing to deliver medication to a patient in a timely manner.

(4) Staff at Respondent confirmed medication delivery dates on three separate occasions and the medication was not delivered to the patient on any of those specified dates. Due to unprecedented and unexpected call and prescription volumes during the relevant time period, patient spent several hours on hold with Respondent regarding the status of the medication and received the medication four (4) days after the first promised delivery date.

(5) The Board further alleges Respondent engaged in unprofessional or unethical conduct by failing to have a functioning auto-refill scheduling program for a period of eight (8) days. When Respondent learned of the failure in the technology, it promptly fixed the issue and the auto-refill scheduling program has been running correctly since that time. Because of the brief lapse in the auto-refill program, a patient enrolled in the program was not contacted to schedule a delivery before running out of medication.

(6) During the relevant time period, Respondent experienced a dramatic and unexpected increase in the number of incoming calls to the pharmacy due to forces outside Respondent's control.

RECEIVED
DEC 10 2021
BOARD OF PHARMACY

EXHIBIT "1"

JILL RHODES
President
Kentucky Board of Pharmacy

12/6/2021
DATE

DocuSigned by:
Van Anderson

11/14/2021
DATE

VAN ANDERSON
Chief Counsel
McKesson Corporation
On Behalf of
RXC ACQUISITION COMPANY
DBA RXCROSSROADS BY MCKESSON
Respondent

RECEIVED
DEC 10 2021
DOCA

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Advanced Accelerator Applications USA, Inc.

Physical Address: 10675 John Jay Hopkins Drive, Suite A103

City: San Diego State: CA Zip: 92121

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 317-452-0364 Website: www.adacap.com

Name of Designated Representative (DR): Tiarra Johnson

Licensing Company Email: TIARRA.JOHNSON@NOVARTIS.COM DR Email: TIARRA.JOHNSON@NOVARTIS.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/19/2021		AL		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
21-L-0154	Alabama Board of Pharmacy

Reason/Charge
Failure to provide notification of a change in designated representative within the required notification period

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Advanced Accelerator Applications USA, Inc.

Provide explanation below:

On November 19, 2021, the Alabama Board of Pharmacy (Board) issued a Final Order against Advanced Accelerator Applications USA, Inc.'s (AAA) Millburn, NJ facility for its failure to notify the Board of a change in designated representative within the required 10 day time period. On December 27, 2021, AAA paid an administrative fine of $1,000. AAA's Alabama license is currently active and in good standing. Enclosed is a copy of the Final Order.

Liana Johnson
Original Signature (electronic, copies or stamps not accepted)

06/14/2024
Date

DocuSign Envelope ID: EB37A073-8E8F-4437-A5E3-A49D9AC70E84

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
ADVANCED ACCELERATOR. APPLICATIONS, USA, INC.	)	BOARD OF PHARMACY
	)	
	)	
Manufacturer	)	
Permit Number 195090	)	Case Number 21-L-0154

FINAL ORDER

On November 21, 2021, this cause came before the Alabama State Board of Pharmacy (hereinafter also referred to as the "Board") on a Complaint against Advanced Accelerator Applications, USA, Inc. (hereinafter also referred to as the "Respondent"). Evidence having been adduced thereon, the Board has determined that the following Findings of Fact and Conclusions of Law are supported by the preponderant weight of evidence and law.

Motion

The Board moved to Amend Count One of the Statement of Charges and Notice of Hearing dated July 15, 2021, and served on the Respondent to read as follows:

"Violating Board Rule 680-X-2.23(2) (h) (ii) by your failure to notify the Board in a timely manner of the change in your Designated Representative, to-wit: the change took place on May 1, 2021, but the Board was not notified until June 30, 2021." The Motion was GRANTED.

Findings of Facts

1. The Respondent is a manufacturer to which the Board issued permit number 195090 and is located at 57 East Willow Street, Millburn, New Jersey 07041

2. The Respondent was notified of the charges on September 3, 2021. The Respondent

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did not attend the administrative hearing and was not represented by counsel at the hearing. (Board's Exhibits One and Two)

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent submitted to the Board a Designated Representative Change/Update Form dated June 29, 2021, stating the effective date of change as 5/01/2021. The Respondent failed to make the change of the designated representative within the ten (10) time period required by Board rule. (Board's Exhibit Three)

Conclusions of Law

1. The Alabama State Board of Pharmacy has jurisdiction of this cause pursuant to Code of Alabama (1975), § 34-23-32, Code of Alabama (1975), § 34-23-92 (12), and Code of Alabama (1975), § 41-22-12.

2. The Respondent was properly notified of the charges and was not represented by counsel at the administrative hearing.

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent's manufacturer permit in the state of Alabama is due to have disciplinary sanctions imposed in that it is guilty of violating Board Rule 680-X-2.23 (2) (h)(ii) by its failure to notify the Board in a timely manner of the change in its Designated Representative, to-wit: the change took place on May 1, 2021 but the Board was not notified until June 30, 2021 .

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ORDER

In accordance with the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED as follows:

1. The Respondent is Ordered to pay the Board an administrative fine of One Thousand ($1,000.00) Dollars within thirty (30) days of this Final Order and future applications for renewal shall not be granted unless said fine has been paid; and

2. Any future violations of this Order, the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rule of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state may, upon hearing and proof thereof, result in further disciplinary sanctions.

DONE and ORDERED, this 19th day of November 2021.

Brenda R. Denson, Pharm. D, President
Alabama State Board of Pharmacy

Copies to:
Advanced Accelerator Applications, USA, Inc
Ms. Donna C. Yeatman, R. Ph., Executive Secretary
Mr. James S. Ward, Esq.
Mr. James F. Hampton, Esq.
Mr. Vance L. Alexander, Esq.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/10/2022		MO		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Missouri Board of Pharmacy		
Reason/Charge				
Distributed drugs into the state without an active license; Failed to provide notification of a change in manager-in-charge in a timely manner				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Advanced Accelerator Applications USA, Inc.				

Provide explanation below:

On June 10, 2022, the Missouri Board of Pharmacy (Board) issued an Order granting a probated license to Advanced Accelerator Applications USA, Inc.'s (AAA) Millburn, NJ facility. AAA allowed its Missouri license to expire on October 31, 2021 and distributed drugs into the state without an active Missouri license. In addition, AAA failed to notify the Board of a change in manager-in-charge in a timely manner. AAA filed a new application for licensure on February 1, 2022 and the Board issued a new license subject to probation for a period of two years. AAA is required to report to the Board once every six months stating whether it has complied with all terms and conditions of probation. AAA's license will be fully restored upon the expiration of the probation if all requirements have been satisfied.

Liana Johnson
Original Signature (electronic, copies or stamps not accepted)

06/14/2024
Date

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Acting Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

USPS First Class and
CERTIFIED MAIL
RETURN RECEIPT REQUESTED
9314 8699 0430 0096 1081 65

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

June 10, 2022

Michael Rossi, President
Advanced Accelerator Applications USA Inc
[redacted]
Milburn, NJ 07860

Dear Mr. Rossi:

Enclosed is a copy of the fully executed **ORDER OF THE MISSOURI BOARD OF PHARMACY ISSUING ADVANCED ACCELERATOR APPLICATION USA INC. A DRUG DISTRIBUTOR LICENSE SUBJECT TO PROBATION** regarding the discipline of Missouri pharmacy permit #2022003970. The Agreement is effective June 9, 2022. The drug distributor registration is enclosed.

You should review each term of this order and comply with the requirements as set forth. Compliance with this Agreement is your responsibility; reminders will not be sent from this office. Failure to comply with the terms of this Agreement may result in a violation hearing before the Board.

Enclosed are two copies of the Licensee Report of Discipline Compliance form for use in submitting the six-month reports required by the Order. Your first report is due July 1, 2022. This form may be copied as needed for future use, and is also available on our website at www.pr.mo.gov/pharmacists.asp, click Applications and Forms, under Miscellaneous.

Sincerely,

Jennifer Boehm

JENNIFER BOEHM
ADMINISTRATIVE COORDINATOR

Enclosure

cc: Kelly Ann Moore, MIC CERTIFIED MAIL TRACKING NO. 9314 8699 0430 0096 1089 81
Daryl Hylton, Attorney

BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI

IN RE:	)
	)
ADVANCED ACCELERATOR APPLICTIONS	)
USA INC.	)
57 East Willow St.	)
Milburn, NJ, 07041	)

ORDER OF THE MISSOURI BOARD OF PHARMACY
ISSUING ADVANCED ACCELERATOR APPLICTION USA INC.
A DRUG DISTRIBUTOR LICENSE
SUBJECT TO PROBATION

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug distributor license, license number 2022003970, to ADVANCED ACCELERATOR APPLICTIONS USA INC. (Advanced) pursuant to the provisions of Section 324.038, RSMo. As set forth in Section 324.038, RSMo, Advanced may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to Advanced. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of Advanced's drug distributor license. Should Advanced file a written request for review of this Order, the terms and conditions of the Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. Advanced filed an application for licensure as a drug distributor on February 1, 2022. Advanced was previously licensed by the Board, but allowed its license to expire on October 31, 2021. The license issued pursuant to this Order is in response to the February 1, 2022 application.

3. During the period November 3, 2021 through January 12. 2021, Advanced distributed drugs to Missouri hospitals on approximately 40 occasions without holding an active Missouri drug distributor license.

4. Section 338.333, RSMo prohibits acting as a drug distributor without first obtaining a license to do so from Missouri.

5. Further, Advanced failed to timely notify the Board that its manager-in-charge changed on May 1, 2021.

6. 20 CSR 2220-5.030(2)(E) states in pertinent part:

> When the person who is manager-in-charge resigns or is terminated from the position, the holder of the license shall immediately notify the board office of the resignation or termination of the manager-in-charge and by notarized affidavit give the name of the new manager-in-charge.

7. In addition, on November 19, 2021 Advanced was disciplined by the Alabama Board of Pharmacy for late notification that its "designated representative" changed.

8. Advanced's conduct as alleged above is cause for the Board to deny Advanced licensure as a drug distributor pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:

> 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer,

owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of, or assisting or enabling ay person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

9. Section 324.038.1, RSMo, provides in pertinent part:

1. Whenever a board within or assigned to the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license, may, at its discretion, issue to an applicant a license subject to probation.

ORDER

10. Based on the foregoing, it is the ORDER of the Missouri Board of Pharmacy that, in lieu of denying licensure as a drug distributor, the Board hereby issues Advanced drug distributor license number 2022003970 subject to PROBATION for a period of TWO YEARS. This Order shall become effective on the date issued. The terms of probation shall be:

A. Advanced shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

B. Advanced shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If, after disciplinary sanctions have been imposed, Advanced fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

D. Advanced shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

E. Advanced agrees that it will make itself available for inspection by inspectors employed by the Missouri Board of Pharmacy between January 1 and December 31 of each year it is under discipline. This also includes the beginning and ending years of the discipline. The Respondent shall reimburse the

Board for travel expenses and meals incurred to facilitate these inspections including, but not limited to, airfare, lodging, shuttle, and transportation expenses within seven (7) days of being provided a notice and valid receipts for said expenses. Travel expenses and meals shall be governed by the recognized Missouri Office of Administration guidelines for state employee travel.

F. Advanced shall make a representative available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Advanced will be notified and given sufficient time to arrange these meetings.

G. Advanced's failure to comply with any condition of discipline set forth herein constitutes a violation of this Order.

11. Upon the expiration of said probation, Advanced's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that Advanced has violated any term or condition of this Order, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Advanced

12. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

13. If the Board determines that Advanced has violated a term or condition of this Order, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not

bound by this Order in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Order occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Order has occurred.

14. The Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

SO ORDERED this 9th day of June, 2022.

BOARD SEAL

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR
MISSOURI BOARD OF PHARMACY

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Advanced Accelerator Applications USA, Inc.

Address: 57 E Willow Street City: Millburn State: NJ Zip: 07041

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Advanced Accelerator Applications S.A..

Corporation/Organization Name: Advanced Accelerator Applications USA, Inc.

Mailing Address: 10675 John Jay Hopkins Drive, Suite A103

City: San Diego State: CA Zip: 92121

Telephone: 317-452-0364 Email: TIARRA.JOHNSON@NOVARTIS.COM

Contact Person Name: Tiarra Johnson

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: See Attachments A and B	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment C		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment E		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Attachment F	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment G	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019 Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Advanced Accelerator Applications USA, Inc

Facility Name

Tiarra Johnson

Print Name of Authorized Person Submitting Application

Tiarra Johnson

Original signature of Authorized Person (copies or stamps not accepted)

06/14/2024

Date

Board Use Only	Date Received: 6/20/24	Amount: $1,000.00 ✓

Attachment A

Nature of Business and FDA Registration

Advanced Accelerator Applications USA, Inc. (AAA) is a manufacturer of non-controlled prescription drugs. AAA's San Diego, CA facility will not physically manufacture products. All products will be manufactured at AAA's Millburn, NJ facility. AAA's San Diego, CA facility will physically ship its own-labeled products to customers. **Enclosed is proof of FDA labeler code registration.**

+Physical Manufacturing Location

Advanced Accelerator Applications USA, Inc
[redacted] Street, Millburn, NJ 07041
FDA registration #: 3012484129

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through April 11, 2024

You have searched Finished drug products

Search Results: *'ADVANCED ACCEL'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name
+ LOCAMETZ	69488-017-61	25 ug/1	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	NDA215841	Advanced Accelerator Applications USA, Inc	69488-017	kit for the preparation of gallium Ga 68 gozetotide	GOZETOTIDE
+ Lutathera	69488-003-01	10 mCi/mL	INJECTION	INTRAVENOUS	NDA208700	Advanced Accelerator Applications USA, Inc	69488-003	Lutetium Lu 177 dotatate	LUTETIUM OXODOTREOTIDE LU-177
+ NETSPOT	69488-001-40		KIT	INTRAVENOUS	NDA208547	Advanced Accelerator Applications USA, Inc	69488-001	68Ga-DOTATATE	
+ PLUVICTO	69488-010-61	27 mCi/mL	INJECTION, SOLUTION	INTRAVENOUS	NDA215833	Advanced Accelerator Applications USA, Inc	69488-010	lutetium Lu 177 vipivotide tetraxetan	LUTETIUM LU-177 VIPIVOTIDE TETRAXETAN

Showing 1 to 4 of 4 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Attachment C

Corporation Information

Corporate Officers:

Geoffrey Towle
President

Eduard Marti
Treasurer

Michael Helfand
Assistant Treasurer

Parent Company:

Advanced Accelerator Applications S.A.
Percent ownership: 100

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ADVANCED ACCELERATOR APPLICATIONS USA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ADVANCED ACCELERATOR APPLICATIONS USA, INC." WAS INCORPORATED ON THE NINTH DAY OF APRIL, A.D. 2014.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5513881 8300

SR# 20233278892

Authentication: 203989041

Date: 08-17-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment G

Regarding the Resident State License

There are two licensing agencies in California. The California Department of Public Health issues manufacturer licenses. However, the California Department of Public Health will not issue a manufacturer license to a facility that does not physically manufacture product on-site. The California board of Pharmacy issues wholesaler and 3PL licenses. Manufacturers are exempt from the California Board of Pharmacy licensing requirements. As such, a resident state license cannot be provided. Below and enclosed is documentation from the licensing agencies.

California Pharmacy Law

4160. Wholesaler or Third-Party Logistics Provider: License Required

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf

Matos, Samanta

From: Yamada, Anna@DCA <Anna.Yamada@dca.ca.gov>
Sent: Wednesday, June 13, 2018 5:56 PM
To: Matos, Samanta (PLS)
Subject: FW: Question Regarding Inspection Process For Virtual Manufacturers

Follow Up Flag: Follow up
Flag Status: Completed

Hello,

The Board does not license manufacturers. The Board does license wholesalers- please refer to BPC 4160 and CCR 1780. California pharmacy law book : http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf

Thank you,
Anna Yamada

Anna Yamada, Pharm. D., Inspector
California State Board of Pharmacy
(626) 446-2076 | FAX (626) 446-2291 | www.pharmacy.ca.gov
Be Aware and Take Care: Talk to your Pharmacist!

From: WIsstatus@DCA
Sent: Wednesday, June 13, 2018 10:21 AM
To: Matos, Samanta (PLS) <matos@porziols.com>
Cc: DCA, Ask Inspector@DCA <Ask.Inspector@dca.ca.gov>
Subject: RE: Question Regarding Inspection Process For Virtual Manufacturers

Good Afternoon,

Your email is being forwarded to our inspector desk to be handled.

Regards,

Elizabeth Schlosser, Site Licensing Analyst
California State Board of Pharmacy
(916) 574-7734 | FAX (916) 574-8617 | www.pharmacy.ca.gov
Be Aware and Take Care: Talk to your Pharmacist!

From: Matos, Samanta (PLS) [mailto:matos@porziols.com]
Sent: Tuesday, June 12, 2018 12:16 PM
To: Schlosser, Elizabeth@DCA <Elizabeth.Schlosser@dca.ca.gov>
Subject: Question Regarding Inspection Process For Virtual Manufacturers

Hi Elizabeth,

I hope all is well. **Could you please provide some information regarding the inspection process for a virtual manufacturer located in the state of California?** One of my clients submitted their initial wholesaler application to your office a couple of weeks ago. **Would their office space get inspected? If so, what does the inspector need for facilities that are not physically handling products? How do applicants schedule an inspection?**

Thank you in advance for your time and assistance.

Regards,

Samanta

DocuSign Envelope ID: 8AA8F04E-CB98-4934-A53E-06F17E91A84F

Liberty Mutual

CHANGE RIDER

To be attached to and form a part of surety bond number 019074419, dated the 16th day of October, 2020, issued by Liberty Mutual Insurance Company, a Massachusetts stock insurance company, as surety (the "Surety"), on behalf of ADVANCED ACCELERATOR APPLICATIONS USA, INC., as principal (the "Principal") in favor of NEVADA STATE BOARD OF PHARMACY, as obligee (the "Obligee").

The Principal and the Surety hereby consent to changing the attached bond as follows:

remove site service location:

8250 Challenger Drive, Indianapolis, IN 46241

add site service location:

10675 John Jay Hopkins Drive, Suite A103, San Diego, CA 92121

This change is effective 16th day of May, 2024. The attached bond shall be subject to all of its terms, conditions and limitations except as herein modified.

IN WITNESS WHEREOF, said Principal and Surety have caused these presents to be duly signed and sealed this 4th day of June, 2024.

WITNESS / ATTEST:

DocuSigned by:
Lisa A. Butler
193B31154C3A422...
Lisa A. Butler, Witness

ADVANCED ACCELERATOR APPLICATIONS USA, INC.

(Principal)
By: DocuSigned by: Eduard Marti (Seal)
Name: Eduard Marti
Title: US Treasurer and Deputy CCFO

LIBERTY MUTUAL INSURANCE COMPANY

(Surety)
By: DocuSigned by: Elizabeth P. Cervini
21BE4801DCCA4...
Attorney-in-Fact
Elizabeth P. Cervini, Attorney-in-Fact

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS
Seal No. 5865

ACCEPTED:

(Obligee)

By: (Seal)
Name:
Title:

Date:

LMIC-3000 Rev. 03/04

DocuSign Envelope ID: 8AA8F04E-CB98-4934-A53E-06F17E91A84F

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8209978-019008**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Christine M. Hrusovsky, David A. Johnson; David C. Rosenberg; Denise M. Bruno; Elizabeth B. Pendleton; Elizabeth P. Cervini; Harry C. Rosenberg; James M. DiSciullo; John E. Rosenberg; Jonathan F. Black; Julia R. Burnet; Matthew J. Rosenberg; Melissa J. Hinde; Stephanie S. Helmig

all of the city of Wayne state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 19th day of April, 2023

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 19th day of April 2023 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 4th day of June 2024

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 019074419

Application/License No. WH02246

ADVANCED ACCELERATOR APPLICATIONS USA, INC., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
57 E. Willow Street, Millburn, NJ 07041, as
Address of Applicant/Principal
PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY, a
Surety Company
corporation organized under the laws of the ~~state~~ of Commonwealth of Massachusetts
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1001 4th Avenue, Suite 1700, Seattle, WA 98154 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 16, 2020.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of October, 20 20.

APPLICANT/PRINCIPAL

ADVANCED ACCELERATOR APPLICATIONS USA, INC.

Authorized Representative

SURETY COMPANY

LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Elizabeth P. Cervini, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Cindy Walsh, Witness

Witness Zach Grainda, Witness

Countersigned by:

N/A
Nevada Resident Agent

HILLARY J. HALL
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 4/4/2021

Posted February 20, 2020

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8202271-019008**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Jonathan F. Black; Stephanie S. Helmig; Joyce M. Houghton; Matthew J. Rosenberg; Denise M. Bruno; Julia R. Burnet; Elizabeth P. Cervini; James M. DiSciullo; Melissa J. Hinde; Christine M. Hrusovsky; David A. Johnson; Harry C. Rosenberg; David C. Rosenberg; John E. Rosenberg; Nolan P. Steele

all of the city of Wayne state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 2nd day of October, 2019

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 2nd day of October, 2019 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Teresa Pastella, Notary Public
Upper Merion Twp., Montgomery County
My Commission Expires March 28, 2021
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

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Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 16th day of October, 2020

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co_062018

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

To confirm the validity of this Power of Attorney call 1-610-832-8240 between 9:00 am and 4:30 pm EST on any business day.

Liberty Mutual SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT — DECEMBER 31, 2019

Assets

Cash and Bank Deposits	$778,754,989
*Bonds — U.S Government	2,780,808,610
*Other Bonds	12,645,608,792
*Stocks	16,385,435,431
Real Estate	235,608,378
Agents' Balances or Uncollected Premiums	6,217,983,641
Accrued Interest and Rents	102,273,390
Other Admitted Assets	11,957,106,292
Total Admitted Assets	**$51,103,579,523**

Liabilities

Unearned Premiums		$8,007,146,482
Reserve for Claims and Claims Expense		21,532,853,787
Funds Held Under Reinsurance Treaties		507,868,920
Reserve for Dividends to Policyholders		1,143,826
Additional Statutory Reserve		125,722,000
Reserve for Commissions, Taxes and Other Liabilities		4,117,460,075
Total		**$34,292,195,090**
Special Surplus Funds	$32,768,443	
Capital Stock	10,000,075	
Paid in Surplus	10,044,978,933	
Unassigned Surplus	6,723,636,983	
Surplus to Policyholders		**16,811,384,434**
Total Liabilities and Surplus		**$51,103,579,524**

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the state of Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2019, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 27th day of March, 2020.

T A Mikolajewski

Assistant Secretary

S-1262LMIC/a 3/20

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Advanced Accelerator Applications USA, Inc.

Pharmacy/Wholesaler License # (if applicable): Pending

Physical Address: 10675 John Jay Hopkins Drive, Suite A103

City: San Diego State: CA Zip: 92121

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 317-452-0364 Website: www.adacap.com

Licensing Company Email: TIARRA.JOHNSON@NOVARTIS.COM

Section 2: Personal Information

First: Tiarra Middle: Renee Last: Johnson

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: 10675 John Jay Hopkins Drive, Suite A103

City: San Diego State: CA Zip: 92121

Telephone: 317-452-0364 Email: TIARRA.JOHNSON@NOVARTIS.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Institute of Technology		06/15 - 02/16	
Address	**City**	**State**	**Zip**
564 Herndon Ave.	Clovis	CA	93612
Diploma/Degree obtained, if any			
Certification in Culinary Arts			
School Name		**From - To (MM/YY – MM/YY)**	
Clovis East High School		08/04 - 06/08	
Address	**City**	**State**	**Zip**
2940 Leonard Ave	Clovis	CA	93619
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/2024 - present	[redacted] Hillery Dr, Apt 19308	San Diego	CA	92126
02/24 - 5/2024	[redacted] Plum Dr Unit F	Indianapolis	IN	46221
11/8 - 02/24	[redacted] Trunk Way Unit G	Indianapolis	IN	46221
01/18 - 11/18	[redacted] Hanna Village Dr Apt G	Indianapolis	IN	46227
01/17 - 11/18	[redacted]	McCordsville	IN	46066
01/16 - 1/17	[redacted] N Bungalow LN	Fresno	CA	93704
01/16 - 01/16	[redacted] W Barstow Ave Apt 224	Clovis	CA	93612
08/14 - 01/16	[redacted] W Barstow Ave Apt 124	Clovis	CA	93612
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Advanced Accelerator Applications USA, Inc.			05/2024 - Present
Business Address	**City**	**State**	**Zip**
10675 John Jay Hopkins Drive, Suite 103A	San Diego	CA	92121
Phone	**Title**	**Number of Employed Hours**	
317-452-0364	Shipping and Receiving Lead	40 hours/week (full-time)	

Description of Duties
Coordination of shipping, receiving, storage and processing of goods including but not limited to performing periodic inventory counts and reconciliation of discrepancies and staging of material for production purposes.

Business Name			From - To (MM/YY – MM/YY)
Novartis Manufacturing LLC			12/2022 - 5/2024
Business Address	**City**	**State**	**Zip**
8520 Challenger Drive	Indianapolis	IN	46241
Phone	**Title**	**Number of Employed Hours**	
317-452-0364	Shipping and Receiving Lead	40 hours/week (full-time)	

Description of Duties
Coordination of shipping, receiving, storage and processing of goods including but not limited to performing periodic inventory counts and reconciliation of discrepancies and staging of material for production purposes.

Business Name			From - To (MM/YY – MM/YY)
Becton, Dickinson and Company			01/2021 - 01/2022
Business Address	**City**	**State**	**Zip**
2350 Reeves Rd	Plainfield	IN	46168
Phone	**Title**	**Number of Employed Hours**	
317-561-2900	Team Leader TJ	40 hours/week (full-time)	

Description of Duties
Supervising a team that is responsible for the packaging within the shipping system, daily component packaging, and customer customization order filing within the delivery and packing system. Scans barcodes of shipping modules to the SAP system for record keeping. Completes daily inbound receiving of product and packages and notifies recipients accordingly. Pulling, packing, and loading.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Should have 6,000 hrs by Sept.

Business Name			– MM/YY)
Business Address	**City**		**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Advanced Accelerator Applications USA, Inc.			05/2024 - Present
Business Address	**City**	**State**	**Zip**
10675 John Jay Hopkins Drive, Suite 103A	San Diego	CA	92121
Phone	**Title**		**Number of Employed Hours**
317-452-0364	Shipping and Receiving Lead		40 hours/week (full-time)

Description of Duties
Coordination of shipping, receiving, storage and processing of goods including but not limited to performing periodic inventory counts and reconciliation of discrepancies and staging of material for production purposes.

Business Name			From - To (MM/YY – MM/YY)
Novartis Manufacturing LLC			12/2022 - 5/2024
Business Address	**City**	**State**	**Zip**
8520 Challenger Drive	Indianapolis	IN	46241
Phone	**Title**		**Number of Employed Hours**
317-452-0364	Shipping and Receiving Lead		40 hours/week (full-time)

Description of Duties
Coordination of shipping, receiving, storage and processing of goods including but not limited to performing periodic inventory counts and reconciliation of discrepancies and staging of material for production purposes.

Business Name			From - To (MM/YY – MM/YY)
Becton, Dickinson and Company			01/2021 - 01/2022
Business Address	**City**	**State**	**Zip**
2350 Reeves Rd	Plainfield	IN	46168
Phone	**Title**		**Number of Employed Hours**
317-561-2900	Team Leader TJ		40 hours/week (full-time)

Description of Duties
Supervising a team that is responsible for the packaging within the shipping system, daily component packaging, and customer customization order filing within the delivery and packing system. Scans barcodes of shipping modules to the SAP system for record keeping. Completes daily inbound receiving of product and packages and notifies recipients accordingly. Pulling, packing, and loading.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

06/14/2024
Date

I, Tiarra Johnson, **certify that as the designated representative for**

Advanced Accelerator Applications USA, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TJ I am at least 21 years of age;
3. TJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Tiarra Johnson
Print Name (First, Last)

Tiarra Johnson
Original Signature (electronic, copies or stamps not accepted)

06/14/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiarra Johnson
Print Name (First, Last)

Tiarra Johnson
Original Signature (electronic, copies or stamps not accepted)

06/14/2024
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Diego

I, Tiarra Johnson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Tiarra Johnson
Original Signature

06/14/2024
Date

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of: California
County of: San Diego
Subscribed and Sworn to before me this 14th day of June, 2024

Notary Public Signature

MATILDA HERNANDEZ
Commission No 2331047
NOTARY PUBLIC - CALIFORNIA
SAN DIEGO COUNTY
Commission Expires August 2, 2024

(Seal)

Tiarra Johnson

Shipping and Receiving Lead

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Ajenat Pharmaceuticals, LLC

Physical Address: 203 N. Marion Street

City: Tampa State: FL Zip: 33602

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: under construction

Name of Designated Representative (DR): ~~Scott Joseph White~~ Ravi Kumar Tirlangi

Licensing Company Email: AJE@slsny.com DR Email: sjw@ajenatpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: US Government		☒ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Scott Joseph White

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: FL

Parent Company (if any): Jugal Kishore Taneja (63% ownership) & Supriya Subarwal Taneja (34% ownership)

Corporation/Organization Name: Ajenat Pharmaceuticals, LLC

Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Email: AJE@slsny.com

Contact Person Name: Christine Cannon

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: NDC Labeler Code: 82983	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A - no CS	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A - no MDEG	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A - no MDEG	✓	✓	✓	✓
N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Ajenat Pharmaceuticals, LLC

Facility Name

Scott Joseph White

Print Name of Authorized Person Submitting Application

Scott White

Original signature of Authorized Person (copies or stamps not accepted)

10/20/23

Date

Board Use Only	Date Received: 11/9/23	Amount: $1000 check 687

From: **Supriya Subarwal Taneja** sst@ajenatpharma.com
Subject: Fw: Labeler Code Request Approved
Date: September 12, 2022 at 12:56 PM
To: ravit@belcherpharma.com, Scott White sjw@ajenatpharma.com

Ravi - Can you please help finalize this for me?

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Thursday, September 8, 2022 10:42 PM
To: Supriya Subarwal Taneja <sst@ajenatpharma.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 08-SEP-2022
Labeler DUNS: 118777896
Labeler Name: AJENAT PHARMACEUTICALS LLC
Labeler Code Assigned: 82983

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Verified
11/16/23 M.H

Company Particulars

Ajenat Pharmaceuticals LLC

Corporate Address: 203 N Marion Street, Tampa, FL 33602 USA
FEIN: 88-3576414
under construction

Drug Labeler Code: 82983
Incorporation State: FL
Incorporation Date: 8/4/2022

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
TAF	203 N. Marion Street Tampa, FL 33602 County: Hillsborough	N/A	N/A - No CS		No	(813) 418-9034	(727) 544-3595

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Scott Joseph White	[redacted]	Vice President Commercial Operations	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Jugal Kishore Taneja	[redacted]	President	66	No	[redacted]		
Supriya Subarwal Taneja		General Counsel	34	No			

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Scott Joseph White	[redacted]	Vice President Commercial Operations	No	[redacted]		
Jugal Kishore Taneja		President	No			
Supriya Subarwal Taneja		General Counsel	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
CT Corporation			

3PLS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Rainbow Gold, Inc.	115 Grimes Drive Guntersville, AL 35976					

For licensing issues, please contact State License Servicing, LLC (845) 544-2482 AJE@slsny.com

State of Florida
Department of State

I certify from the records of this office that AJENAT PHARMACEUTICALS LLC is a limited liability company organized under the laws of the State of Florida, filed on August 4, 2022.

The document number of this limited liability company is L22000342219.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023, that its most recent annual report was filed on April 20, 2023, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourth day of August, 2023

Secretary of State

Tracking Number: 5489492658CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Board Sealed Verification of License Home State

Florida dbpr Department of Business & Professional Regulation

Drugs

Talla

Melanie S. Griffin, Secretary

Ron DeSantis, Governor

October 27, 2023

NAME: **AJENAT PHARMACEUTICALS LLC**

ADDRESS: 203 N MARION STREET, TAMPA, FL 33602

PROFESSION: PRESCRIPTION DRUG MANUFACTURER - VIRTUAL

LICENSE NUMBER: 45:33

STATUS: CURRENT

ISSUE DATE: JULY 27, 2023

EXPIRATION DATE: JULY 31, 2025

To Whom It May Concern:

The license is in a CURRENT status and EXPIRES on 7/31/2025.

Verification by:

Rebecca J. Burnett

Rebecca J. Burnett
Regulatory Specialist Supervisor/Consultant
Florida Department of Business and Professional Regulation

To Verify Discipline: You may also access online verification at https://www.myfloridalicense.com/wl11.asp?mode=0&SID=

THE OFFICIAL SITE OF THE FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION



dbpr Department of Business & Professional Regulation

ONLINE SERVICES

Apply for a License
Verify a Licensee
View Food & Lodging Inspections
File a Complaint
Continuing Education Course Search
View Application Status
Find Exam Information
Unlicensed Activity Search
AB&T Delinquent Invoice & Activity List Search

LICENSEE DETAILS

12:46:43 PM 8/28/2023

Licensee Information

Name:	**AJENAT PHARMACEUTICALS LLC (Primary Name)**
Main Address:	**1751 STATE ROUTE 17A, SUITE 3 FLORIDA New York 10921**
County:	**OUT OF STATE**
License Location:	**203 N MARION STREET TAMPA FL 33602**
County:	**HILLSBOROUGH**

License Information

License Type:	**Prescription Drug Manufacturer - Virtual**
Rank:	**Rx Drug Manu V**
License Number:	**4533**
Status:	**Current**
Licensure Date:	**07/27/2023**
Expires:	**07/31/2025**

Alternate Names

View Related License Information
View License Complaint

2601 Blair Stone Road, Tallahassee FL 32399 :: Email: Customer Contact Center :: Customer Contact Center: 850.487.1395

The State of Florida is an AA/EEO employer. Copyright 2007-2010 State of Florida. Privacy Statement

Under Florida law, email addresses are public records. If you do not want your email address released in response to a public-records request, do not send electronic mail to this entity. Instead, contact the office by phone or by traditional mail. If you have any questions, please contact 850.487.1395. *Pursuant to Section 455.275(1), Florida Statutes, effective October 1, 2012, licensees licensed under Chapter 455, F.S. must provide the Department with an email address if they have one. The emails provided may be used for official communication with the licensee. However email addresses are public record. If you do not wish to supply a personal address, please provide the Department with an email address which can be made available to the public. Please see our Chapter 455 page to determine if you are affected by this change.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100731828

Application/License No. _____

AJENAT PHARMACEUTICALS LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 203 N MARION ST TAMPA, FL, 33602 (Address of Applicant/Principal), as PRINCIPAL, and AMERICAN CONTRACTORS INDEMNITY COMPANY (Surety Company), a corporation organized under the laws of the state of California (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 801 S. Figueroa Street, Suite 700, Los Angeles, CA 90017 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 3/16/2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of March, 2023.

AMERICAN CONTRACTORS INDEMNITY CO. INCORPORATED SEPT. 25, 1990 CALIFORNIA

APPLICANT/PRINCIPAL

AJENAT PHARMACEUTICALS LLC

Authorized Representative

SURETY

AMERICAN CONTRACTORS INDEMNITY COMPANY

Surety Company's Representative

BONNIE ROBBINS, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

TOKIO MARINE HCC

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS:
That American Contractors Indemnity Company of the State of California, a California corporation, does hereby appoint,

BONNIE ROBBINS

its true and lawful Attorney-in-Fact, with full authority to execute on its behalf bond number 100731828, issued in the course of its business and to bind the Company thereby, in an amount not to exceed Twenty-five thousand and 00/100 ($25,000.00).

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the Board of Directors of AMERICAN CONTRACTORS INDEMNITY COMPANY at a meeting duly called and held on the 1st day of September, 2011.

"Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings, including any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts, and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached."

The Attorney-in-Fact named above may be an agent or a broker of the Company. The granting of this Power of Attorney is specific to this bond and does not indicate whether the Attorney-in-Fact is or is not an appointed agent of the Company.

IN WITNESS WHEREOF, American Contractors Indemnity Company has caused its seal to be affixed hereto and executed by its President on this 18th day of April, 2022.

AMERICAN CONTRACTORS INDEMNITY CO. INCORPORATED SEPT. 25, 1990 CALIFORNIA

State of California
County of Los Angeles

AMERICAN CONTRACTORS INDEMNITY COMPANY

By: _____
Adam S. Pessin, President

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

On this 18th day of April, 2022, before me, Sonia O. Carrejo, a notary public, personally appeared Adam S. Pessin, President of American Contractors Indemnity Company, who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of CALIFORNIA that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature _____ (seal)

SONIA O. CARREJO Notary Public - California Los Angeles County Commission # 2398710 My Comm. Expires Apr 23, 2026

I, Klo Lo, Assistant Secretary of American Contractors Indemnity Company, do hereby certify that the Power of Attorney and the resolution adopted by the Board of Directors of said Company as set forth above, are true and correct transcripts thereof and that neither the said Power of Attorney nor the resolution have been revoked and they are now in full force and effect.

IN WITNESS WHEREOF, I have hereunto set my hand this 22nd day of March, 2023.

Bond No. 100731828

Agency No. 13955

AMERICAN CONTRACTORS INDEMNITY CO. INCORPORATED SEPT. 25, 1990 CALIFORNIA

_____
Klo Lo, Assistant Secretary

HCCSOZZPOAACIC04/2022

visit tmhcc.com/surety for more information

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Ajenat Pharmaceuticals LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 203 N. Marion Street

City: Tampa State: FL Zip: 33602

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: under construction

Licensing Company Email: AJE@SLSNY.COM

Section 2: Personal Information

First: Ravi Kumar Middle: Last: Tirlangi

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Cypress Bridge Dr

City: Odessa State: FL Zip: 33556

Telephone: [redacted] Email: ravit@ajenatpharma.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Andhra University		Graduated April 2002	
Address	City	State	Zip
Visakhapatnam, Andhra Pradesh 530003, India	N/A	N/A	N/A
Diploma/Degree obtained, if any			
MS Pharmaceutical Chemistry			
School Name		From - To (MM/YY – MM/YY)	
BVK College		08/1996-08/1999	
Address	City	State	Zip
Dwaraka Nagar	Visakhapatnam	AP,India	530016
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2023 - Present	[redacted] Cypress Bridge Dr	Odessa	FL	33556
From - To (MM/YY – MM/YY)		City	State	Zip
06/2022 - 08/2023	[redacted] Promenade Parkway	Odessa	FL	33556
From - To (MM/YY – MM/YY)		City	State	Zip
06/2021 - 06/2022	[redacted] Beluga Bay Dr	Odessa	FL	33556
From - To (MM/YY – MM/YY)		City	State	Zip
07/2018 - 06/2021	[redacted] Red Orchard Ct	Tampa	FL	33635
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Ajenat Pharmaceuticals LLC			03/2024 - Present
Business Address	**City**	**State**	**Zip**
203 N. Marion Street	Tampa	FL	33602
Phone	**Title**	**Number of Employed Hours**	
(813) 418-9034	Director Regulatory Compliance	~ 280 Hours	

Description of Duties
1. Actively involved and monitor of the daily operations of the wholesaler.
2. Verify the inbound and out bound logbooks.

Business Name			From - To (MM/YY – MM/YY)
BPI Labs and Belcher Pharmaceuticals, LLC			06/2011 - 02/2024
Business Address	**City**	**State**	**Zip**
12393 Belcher Rd S. Suite 450	Largo	FL	33773
Phone	**Title**	**Number of Employed Hours**	
(662) 661-3232	Associate Director - Regulatory Affairs	~ 26,440 Hours	

Description of Duties
1. Actively involved and monitor of the daily operations of the facility.
2. Verify the inbound and outbound logbooks.
3. Verify the compliance of federal and state authority requirements

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
		~	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Ravi Kumar Tirlangi, **certify that as the designated representative for**

Ajenat Pharmaceuticals LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RKT I am at least 21 years of age;
3. RKT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RKT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RKT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RKT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RKT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ravi Kumar Tirlangi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/31/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ravi Kumar Tiriangi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/31/24

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pinellas

I, Ravi Kumar Tiriangi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Ravi Kumar Tiriangi

05/31/24

Date

Subscribed and Sworn to before me this 31 day of June, 2024

Susan E Marshall

Notary Public Signature

SUSAN E MARSHALL
Notary Public - State of Florida
Commission # HH 114552
My Comm. Expires Apr 19, 2025
Bonded through National Notary Assn.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Ajenat Pharmaceuticals LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Initial App

Physical Address: 203 N. Marion Street

City: Tampa State: FL Zip: 33602

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: Under Construction

Licensing Company Email: AJE@slsny.com

Section 2: Personal Information

First: Supriya Middle: Subarwal Last: Taneja

Alias(es, nicknames, name changes, etc.): N/A

Date of Birt[redacted] SSN or ITI[redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Bayshore Blvd, Suite 2202

City: Tampa State: FL Zip: 33629

Telephone [redacted] Email: sst@ajenatpharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Stetson University College of Law		05/2004 - 12/2006	
Address	**City**	**State**	**Zip**
N/A	Gulfport	FL	N/A
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
Apeejay School of Management / Thames Valley University (London, UK)		08/2000 - 08/2001	
Address	**City**	**State**	**Zip**
Bus Depot, Sector VIII Institutional Area Besides DTC, Sector 8	Dwarka, New Delhi 110077	India	
Diploma/Degree obtained, if any			
Masters in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Apeejay School of Management / Thames Valley University (London, UK)		07/1997 - 06/2000	
Address	**City**	**State**	**Zip**
Bus Depot, Sector VIII Institutional Area Besides DTC, Sector 8	Dwarka, New Delhi 110077	India	
Diploma/Degree obtained, if any			
Bachelors in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Covenant of Jesus and Mary		05/1993 - 03/1997	
Address	**City**	**State**	**Zip**
1, Bangla Sahib Ln, Ashok Place, DIZ Staff Quarters, Connaught Place	New Delhi, Delhi 110001	India	
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2020 - Present	[redacted] Bayshore Blvd, Suite 2202	Tampa	FL	33629
12/2018 - 12/2020	[redacted] Bayshore Blvd, Unit 1801	Tampa	FL	33629
01/2014 -12/2018	[redacted] W Melrose Ave	S Tampa	Fl	33629
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Ajenat Pharmaceuticals, LLC			11/2022 - Present
Business Address	**City**	**State**	**Zip**
203 N. Marion Street	Tampa	FL	33602
Phone	**Title**		
(813) 418-9034	Gneral Counsel / Owner (34%)		

Description of Duties

Provide legal advice on state and federal health care regulatory laws as they pertain to the pharmaceutical industry, including US FDA. Drafted and negotiated agreements for manufacturing and development of generic drugs.

Business Name			From - To (MM/YY – MM/YY)
Belcher Pharmaceuticals, LLC			01/2018 - Present
Business Address	**City**	**State**	**Zip**
6911 Bryan Dairy Rd	Largo	FL	33777
Phone	**Title**		
(727) 471-0850	General Counsel		

Description of Duties

Provide legal advice on state and federal health care regulatory laws as they pertain to the pharmaceutical industry, including US FDA. Drafted and negotiated agreements for manufacturing and development of generic drugs.

Business Name			From - To (MM/YY – MM/YY)
Kaligia Biosciences, LLc			01/2018 - Present
Business Address	**City**	**State**	**Zip**
7441 114th Ave #607a	Largo	FL	33773
Phone	**Title**		
(727) 234-8873	General Counsel		

Description of Duties

Provide legal advice on state and federal health care regulatory laws as they pertain to FDA regulations for medical device manufacturing, and drafting contracts and consent forms for clinical studies related to approval of medical devices.

Business Name			From - To (MM/YY – MM/YY)
CPN Biosciences			01/2015 - 2020
Business Address	**City**	**State**	**Zip**
6925 112th Cir N	Largo	FL	33773
Phone	**Title**		
(757) 234-8880	General Counsel		

Description of Duties

Provide legal advice on state and federal health care regulatory laws as they pertain to CPN's business model. Drafted and negotiated agreements with physician groups and nursing homes.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Suriya Subarwal Taneja

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09-20-2023

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pinellas

I, Supriya TanejA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Suriya Subarwal Taneja

09-20-2023

Date

Subscribed and Sworn to before me this 20th day of September, 2023

Notary Public Signature

SUSAN E MARSHALL
Notary Public - State of Florida
Commission # HH 114552
My Comm. Expires Apr 19, 2025
Bonded through National Notary Assn.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Ajenat Pharmaceuticals LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Initial App

Physical Address: 203 N. Marion Street

City: Tampa State: FL Zip: 33602

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: Under Construction

Licensing Company Email: AJE@slsny.com

Section 2: Personal Information

First: Jugal Middle: Kishore Last: Taneja

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Bayshore Blvd, Unit 1801

City: Tampa State: FL Zip: 33629

Telephone: [redacted] Email: JT@Ajenat.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
New York State		1978	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
Professional Engineering License			

School Name		From - To (MM/YY – MM/YY)	
M.B.M Engineering College		1961 -1966	
Address	**City**	**State**	**Zip**
Air Force Area	Jodhpur, Rajasthan 342011,	India	
Diploma/Degree obtained, if any			
Engineering Degree in Mining and Petroleum			

School Name		From - To (MM/YY – MM/YY)	
Ramjas Higher Secondary School		1955-1961	
Address	**City**	**State**	**Zip**
Karol Bagh	New Delhi	New Delhi	10061
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2007 - Present	[redacted] Bayshore Blvd, Unit 1801	Tampa	FL	33629
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Ajenat Pharmaceuticals, LLC			2010 - Present
Business Address	**City**	**State**	**Zip**
203 N. Marion Street	Tampa	FL	33602
Phone	**Title**		
(813) 418-9034	President / Owner (66%)		
Description of Duties			
50 years of experience in providing management to United States and International businesses with fiscal strategic and operation leadership, focus on developing, licensing, manufacturing, marketing and distributing specialty complex generic drugs in the USA. Responsible for advising on development of abbreviated new drug applications ("ANDA") and new drug applications ("NDA"). I hold the following drug patents in the pharmaceutical industry, that are assigned to the family company, to provide strength, growth and innovation.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jugal Kishore Taneja

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/19/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pinellas

I, Jugal K Taneja, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Jugal Kishore Taneja

10/19/2023

Date

Subscribed and Sworn to before me this 19th day of October 2023

Notary Public Signature

SUSAN E MARSHALL
Notary Public - State of Florida
Commission # HH 114552
My Comm. Expires Apr 19, 2025
Bonded through National Notary Assn.

(Seal)

List of Employees for NV

Scott White

Scott White 04/18/23

Scott White Date

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Alcon Vision, LLC

Physical Address: 6601 Oak Grove Rd Suite 300

City: Fort Worth State: TX Zip: 76134

Mailing Address (if different from physical address): 6201 South Freeway, Mail Stop R9-2

City: Fort Worth State: TX Zip: 76134

Telephone: [redacted] Website: www.alcon.com

Name of Designated Representative (DR): Cody Hutson

Licensing Company Email: [redacted] DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

[redacted]

Original Sign ot accepted)

11-02-2023

Date

6201 South Freeway
Fort Worth, Texas 76134-2099
[redacted]

April 27, 2023

To: All Applicable Boards of Pharmacy
From: Alcon Vision, LLC – Fort Worth, TX
RE: Disciplinary Action Explanation

Name of the Issuing Board: Kansas Board of Pharmacy

Date of the Order: 03/22/2023

Order Description:

6601 Oak Grove Road, Suite 200, Fort Worth, TX 76134

Alcon Vision, LLC applied for a new distribution license with Kansas Board of Pharmacy on or around 03/03/2023. On 3/22/2023 the application was granted by Kansas Board of Pharmacy with the condition that Alcon pay a fine of $2,120. The position held by the Kansas Board of Pharmacy is that this facility distributed drugs and/or devices during the previous 12 months without proper licensure. At such time payment is received by Kansas Board of Pharmacy, the new license will be issued to Alcon.

Explanation:

In 2020, Alcon internally noted that Kansas statutes (65-1643(c)) only required licensure of wholesale distributors and explicitly exempted manufacturers from wholesale distributor license requirements. Because of this, Alcon discontinued its license with Kansas Board of Pharmacy. Kansas implemented new licensure requirements for manufacturers in 2021 (65-1643d and 65-1643(p)).

Alcon Vision, LLC maintains that it has operated in good faith to apply for appropriate licensure in the State of Kansas when it became aware of these statutory amendments. Alcon Vision, LLC is issuing this notice to comply with any potential reporting requirements held by the State Pharmacy Boards or other licensing entities.

Stone, Marisa
Digitally signed by Stone, Marisa
DN: cn=Stone, Marisa, ou=PDF Internal Signing, o=Alcon Vision, LLC
Reason: RS-QG200-FLASH
Date: 2023.05.01 11:26:23 -05'00'

Marisa Stone

Regulatory Affairs Specialist

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

March 22, 2023

Alcon Vision, LLC
Attn: Daniel Copeland
6201 South Freeway, Mail Stop R9-2
Fort Worth Texas 76134

RE: Case No. 23-046

To Whom It May Concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $2,120. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 23-046
Alcon Vision, LLC	)	
	)	
Registration #5-106893	)	

SUMMARY ORDER

NOW, on this 22nd day of March 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Alcon Vision, LLC ("Applicant"), for application for registration as a wholesale distributor in the state of Kansas.

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. On March 3, 2023, the Board received Applicant's application for registration as a wholesale distributor in the State of Kansas ("Applicant's Application").

2. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months." The form directs that if the applicant answered "yes", applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the locations they were sent in Kansas.

3. In conjunction with Applicant's Application, Applicant provided copies of shipping

records for products shipped into Kansas. Applicant reported shipping into Kansas on 56 unique business days during the previous 12 months.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against the application of any wholesale distributor upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.S.A. 65-1643(c), it shall be unlawful for any person to distribute at wholesale any drugs or devices without first obtaining a registration from the Board.

4. Applicant's act of shipping into Kansas prior to being registered as a wholesale distributor is a violation of K.S.A. 65-1643(c) and is a basis to take action against Applicant's Application pursuant to K.S.A. 65-1627(f).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's Application is hereby GRANTED but Applicant is ordered to pay a fine to the Board in the amount of $2,120. Applicant has 30 days from the date of this order to pay the fine and the registration shall be issued upon receipt.

NOTICES

Respondent is hereby notified as follows:

1. Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414,

Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

3/22/2023
Date

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 22nd day of March 2023, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Alcon Vision, LLC
6201 South Freeway, Mail Stop R9-2
Forth Worth Texas 76134

Kansas Board of Pharmacy Staff

6201 South Freeway
Fort Worth, Texas 76134-2099

[redacted]

April 27, 2023

To: All Applicable Boards of Pharmacy
From: Alcon Vision, LLC – Fort Worth, TX
RE: Disciplinary Action Explanation

Name of the Issuing Board: Kansas Board of Pharmacy

Date of the Order: 03/29/2023

Order Description:

6740 Business Parkway, Elkridge, MD 21075

Alcon Vision, LLC applied for a new distribution license with Kansas Board of Pharmacy on or around 03/20/2023. On 3/29/2023, the application was granted by Kansas Board of Pharmacy with the condition that Alcon pay a fine of $5,000. The position held by the Kansas Board of Pharmacy is that this facility distributed drugs and/or devices during the previous 12 months without proper licensure. At such time payment is received by Kansas Board of Pharmacy, the new license will be issued to Alcon.

Explanation:

In 2020, Alcon internally noted that Kansas statutes (65-1643(c)) only required licensure of wholesale distributors and explicitly exempted manufacturers from wholesale distributor licensing requirements. Because of this, Alcon discontinued its license with Kansas Board of Pharmacy. Kansas implemented new licensure requirements for manufacturers in 2021 (65-1643d and 65-1643(p)).

Alcon Vision, LLC maintains that it has operated in good faith to apply for appropriate licensure in the State of Kansas when it became aware of these statutory amendments. Alcon Vision, LLC is issuing this notice to comply with any potential reporting requirements held by the State Pharmacy Boards or other licensing entities.

Stone, Marisa

Digitally signed by Stone, Marisa
DN: cn=Stone, Marisa, ou=PDF Internal Signing, o=Alcon Vision, LLC
Reason: IS+ELK+FLASH
Date: 2023.05.01 11:33:32 -05'00'

Marisa Stone

Regulatory Affairs Specialist

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

March 29, 2023

Alcon Vision, LLC
6740 Business Parkway
Elkridge Maryland 21075

RE: Case No. 23-203

To Whom It May Concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $5000. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 23-203
Alcon Vision, LLC	)	
	)	
Registration No. 5-00733	)	

SUMMARY ORDER

NOW on this 29th day of March 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of Alcon Vision, LLC ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board previously issued Respondent registration number 5-00733 to operate as a wholesale distributor in Kansas, which expired for norenewal on June 30, 2021.

2. On March 20, 2023, the Board received Applicant's application for registration as a wholesale distributor in the State of Kansas ("Respondent's Application").

3. On Respondent's Non-Resident Supplemental S-350 form, Respondent answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months." The form directs that if the applicant answered "yes", the applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the locations they were sent in Kansas.

4. In conjunction with Respondent's Application, Respondent provided copies of shipping records for products shipped into Kansas. Respondent reported shipping into Kansas on 202 unique business days during the previous 12-month period.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against the application of any wholesale distributor upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.S.A. 65-1643(c), it shall be unlawful for any person to distribute at wholesale any drugs or devices without first obtaining a registration from the Board.

4. Respondent's act of shipping into Kansas prior to being registered as a wholesale distributor is a violation of K.S.A. 65-1643(c) and is a basis to take action against Respondent's Application pursuant to K.S.A. 65-1627(f).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Respondent's Application is hereby GRANTED but Respondent is ordered to pay a fine to the Board in the amount of $5,000. Respondent has 30 days from the date of this order to pay the fine and the registration shall be issued upon receipt.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

3/29/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 29th day of March 2023, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Alcon Vision, LLC
6740 Business Parkway
Elkridge Maryland 21075

Alex Bass
Kansas Board of Pharmacy Staff

6201 South Freeway
Fort Worth, Texas 76134-2099

[redacted]

April 27, 2023

To: All Applicable Boards of Pharmacy
From: Alcon Vision, LLC – Fort Worth, TX
RE: Disciplinary Action Explanation

Name of the Issuing Board: Missouri Board of Pharmacy

Date of the Probation Order: 03/16/2023

Order Description:

Oak Grove Road Suite 200

Probation placed on the DRUG DISTRIBUTOR license 2023009875 because this facility was previously licensed up until 10/31/2019. The assumption by the Missouri BoP is that this facility distributed legend drugs and devices during the timeframe between 10/31/2019 and 12/21/2022 without proper licensure. 12/21/2022 is the approximate date of application for the license in question. 03/14/2023 is the date of issuance for the license in question.

6500 Will Rogers Blvd

Probation placed on the DRUG DISTRIBUTOR license 2023009884 because this facility was previously licensed up until 10/31/2019. The assumption by the Missouri BoP is that this facility distributed legend drugs and devices during the timeframe between 10/31/2019 and 12/21/2022 without proper licensure. 12/21/2022 is the approximate date of application for the license in question. 03/14/2023 is the date of issuance for the license in question.

6740 Business Parkway

Probation placed on the DRUG DISTRIBUTOR license 2023009853 because this facility was previously licensed up until 10/31/2019. The assumption by the Missouri BoP is that this facility distributed legend drugs and devices during the timeframe between 10/31/2019 and 12/21/2022 without proper licensure. 12/21/2022 is the approximate date of application for the license in question. 03/14/2023 is the date of issuance for the license in question.

Explanation:

Alcon Vision, LLC maintains that it has operated in good faith to hold appropriate licensure at all times in the State of Missouri. Alcon Vision, LLC is issuing this notice to comply with any potential reporting requirements held by the State Pharmacy Boards or other licensing entities. Alcon Vision, LLC requested, and has been granted, a formal hearing with the Missouri Administrative Hearing Commission to further discuss the probationary status of the licenses in question, the outcome of which is still pending.

Mills, Coy

Digitally signed by Mills, Coy
DN: cn=Mills, Coy, ou=PDF Internal Signing, o=Alcon Vision, LLC
Reason: I attest to the accuracy and integrity of this document
Date: 2023.04.27 15:07:55 -05'00'

Coy Mills

Director, Regulatory Operations / State Licensing

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
9314 8699 0430 0105 6148 30

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

March 16, 2023

Daniel Copeland, MIC
Alcon Vision LLC
6601 Oak Grove Rd. Ste. 200
Fort Worth, TX 76134

Dear Mr. Copeland:

Enclosed is a copy of the fully executed **ORDER OF THE MISSOURI BOARD OF PHARMACY ISSUING ALCON VISION, LLC A DRUG DISTRIBUTOR LICENSE SUBJECT TO PROBATION** and the Missouri drug distributor permit #2023009875. The Order is effective March 14, 2023.

Enclosed are two copies of our Pharmacy and Drug Distributor Report of Discipline Compliance form for use in submitting the six-month reports required by the Agreement. The first report will be due **July 1, 2023**, and each January and July following through the ending date of probation. This form may be copied as needed for future use, and is also available on our website at www.pr.mo.gov/pharmacists, click Applications and Forms, under Miscellaneous.

You should review each term of this Agreement and comply with the requirements as set forth. Compliance with this Agreement is your responsibility; reminders will not be sent from this office. Failure to comply with the terms of this Agreement may result in a violation hearing before the Board.

Sincerely,

Jennifer Boehm

JENNIFER BOEHM
ADMINISTRATIVE COORDINATOR

Enclosure

cc: Daryl Hylton, Attorney
David Endicott, CEO CERTIFIED MAIL TRACKING NO. 9314 8699 0430 0105 6149 60

BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI

IN RE:	)
	)
ALCON VISION, LLC	)
6601 Oak Grove Rd., Ste 200	)
Fort Worth, TX 76134	)

ORDER OF THE MISSOURI BOARD OF PHARMACY
ISSUING ALCON VISION, LLC.
A DRUG DISTRIBUTOR LICENSE
SUBJECT TO PROBATION

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug distributor license, license number 2023009875, to ALCON VISION LLC (Alcon) for its Oak Grove site pursuant to the provisions of Section 324.038, RSMo. As set forth in Section 324.038, RSMo, Alcon may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to Alcon. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of Alcon's drug distributor license. Should Alcon file a written request for review of this Order, the terms and conditions of the Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. Alcon filed an application for licensure as a drug distributor on or about December 21, 2022 for its Oak Grove site. This location was previously licensed by the Board under Alcon Laboratories, Inc., but its license expired on October 31, 2019. The license issued pursuant to this Order is in response to the December 21, 2022 application.

3. During the period October 31, 2019 through November 28, 2022, Alcon distributed legend drugs or devices into Missouri from its Oak Grove site on at least 78 occasions without holding an active Missouri drug distributor license for the site.

4. In addition, during this period, Alcon distributed legend drugs and devices into Missouri from additional unlicensed sites on over 25,000 occasions.

5. Section 338.333, RSMo prohibits acting as a drug distributor without first obtaining a license to do so from Missouri.

6. Sections 338.333 and 338.335, RSMo, requires licenses for each distribution site owned or operated by a wholesale drug distributor.

7. Alcon's conduct as alleged above is cause for the Board to deny Alcon licensure as a drug distributor pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:

> 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section.
>
> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew

or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of, or assisting or enabling ay person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

8. Section 324.038.1, RSMo, provides in pertinent part:

1. Whenever a board within or assigned to the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license, may, at its discretion, issue to an applicant a license subject to probation.

ORDER

9. Based on the foregoing, it is the ORDER of the Missouri Board of Pharmacy that, in lieu of denying Alcon licensure as a drug distributor for its Oak Grove site, the Board hereby issues Alcon drug distributor license number 2023009875 subject to PROBATION for a period of TWO YEARS. This Order shall become effective on the date issued. The terms of probation shall be:

A. Alcon shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

B. Alcon shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If, after disciplinary sanctions have been imposed, Alcon

fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

D. Alcon shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

E. Alcon agrees that it will make itself available for inspection by inspectors employed by the Missouri Board of Pharmacy between January 1 and December 31 of each year it is under discipline. This also includes the beginning and ending years of the discipline. The Respondent shall reimburse the Board for travel expenses and meals incurred to facilitate these inspections including, but not limited to, airfare, lodging, shuttle, and transportation expenses within seven (7) days of being provided a notice and valid receipts for said expenses. Travel expenses and meals shall be governed by the recognized Missouri Office of Administration guidelines for state employee travel.

F. Alcon shall make a representative available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Alcon will be notified and given sufficient time to arrange these meetings.

G. Alcon's failure to comply with any condition of discipline set forth herein constitutes a violation of this Order.

10. Upon the expiration of said probation, Alcon's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines

that Alcon has violated any term or condition of this Order, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Alcon

11. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

12. If the Board determines that Alcon has violated a term or condition of this Order, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Order occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Order has occurred.

13. The Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

SO ORDERED this 14th day of March, 2023.

BOARD SEAL

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR
MISSOURI BOARD OF PHARMACY

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
9314 8699 0430 0105 6147 62

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

March 16, 2023

Aaron Green, MIC
Alcon Vision LLC
6500 Will Rogers Blvd.
Fort Worth, TX 76134

Dear Mr. Green:

Enclosed is a copy of the fully executed **ORDER OF THE MISSOURI BOARD OF PHARMACY ISSUING ALCON VISION, LLC A DRUG DISTRIBUTOR LICENSE SUBJECT TO PROBATION** and the Missouri drug distributor permit #2023009884. The Order is effective March 14, 2023.

Enclosed are two copies of our Pharmacy and Drug Distributor Report of Discipline Compliance form for use in submitting the six-month reports required by the Agreement. The first report will be due **July 1, 2023**, and each January and July following through the ending date of probation. This form may be copied as needed for future use, and is also available on our website at www.pr.mo.gov/pharmacists, click Applications and Forms, under Miscellaneous.

You should review each term of this Agreement and comply with the requirements as set forth. Compliance with this Agreement is your responsibility; reminders will not be sent from this office. Failure to comply with the terms of this Agreement may result in a violation hearing before the Board.

Sincerely,

Jennifer Boehm

JENNIFER BOEHM
ADMINISTRATIVE COORDINATOR

Enclosure

cc: Daryl Hylton, Attorney
David Endicott, CEO CERTIFIED MAIL TRACKING NO. 9314 8699 0430 0105 6149 60

BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI

IN RE:	)
	)
ALCON VISION, LLC	)
6500 Will Rogers Blvd	)
Fort Worth, TX 76134	)

ORDER OF THE MISSOURI BOARD OF PHARMACY
ISSUING ALCON VISION, LLC.
A DRUG DISTRIBUTOR LICENSE
SUBJECT TO PROBATION

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug distributor license, license number 2023009884, to ALCON VISION, LLC (Alcon) for its Will Rogers site pursuant to the provisions of Section 324.038, RSMo. As set forth in Section 324.038, RSMo, Alcon may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to Alcon. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of Alcon's drug distributor license. Should Alcon file a written request for review of this Order, the terms and conditions of the Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. Alcon filed an application for licensure as a drug distributor on or about December 21, 2022 for its Will Rogers site. This location was previously licensed by the Board under Alcon Laboratories, Inc., but its license expired on October 31, 2019. The license issued pursuant to this Order is in response to the December 21, 2022 application.

3. During the period October 31, 2019 through November 29, 2022, Alcon distributed legend drugs or devices into Missouri from its Will Rogers site on over 25,000 occasions without holding an active Missouri drug distributor license for the site.

4. In addition, during this period, Alcon distributed legend drugs and devices into Missouri from additional unlicensed sites.

5. Section 338.333, RSMo prohibits acting as a drug distributor without first obtaining a license to do so from Missouri.

6. Sections 338.333 and 338.335, RSMo, requires licenses for each distribution site owned or operated by a wholesale drug distributor.

7. Alcon's conduct as alleged above is cause for the Board to deny Alcon licensure as a drug distributor pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:

8. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section.

> 1. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew

or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of, or assisting or enabling ay person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

9. Section 324.038.1, RSMo, provides in pertinent part:

1. Whenever a board within or assigned to the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license, may, at its discretion, issue to an applicant a license subject to probation.

ORDER

10. Based on the foregoing, it is the ORDER of the Missouri Board of Pharmacy that, in lieu of denying Alcon licensure as a drug distributor for its Will Rogers site, the Board hereby issues Alcon drug distributor license number 2023009884 subject to PROBATION for a period of TWO YEARS. This Order shall become effective on the date issued. The terms of probation shall be:

A. Alcon shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

B. Alcon shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If, after disciplinary sanctions have been imposed, Alcon fails to keep its drug distributor license current, the period of unlicensed

status shall not be deemed or taken as any part of the time of discipline so imposed.

D. Alcon shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

E. Alcon agrees that it will make itself available for inspection by inspectors employed by the Missouri Board of Pharmacy between January 1 and December 31 of each year it is under discipline. This also includes the beginning and ending years of the discipline. The Respondent shall reimburse the Board for travel expenses and meals incurred to facilitate these inspections including, but not limited to, airfare, lodging, shuttle, and transportation expenses within seven (7) days of being provided a notice and valid receipts for said expenses. Travel expenses and meals shall be governed by the recognized Missouri Office of Administration guidelines for state employee travel.

F. Alcon shall make a representative available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Alcon will be notified and given sufficient time to arrange these meetings.

G. Alcon's failure to comply with any condition of discipline set forth herein constitutes a violation of this Order.

11. Upon the expiration of said probation, Alcon's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that Alcon has violated any term or condition of this Order, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the

discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Alcon

12. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

13. If the Board determines that Alcon has violated a term or condition of this Order, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Order occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Order has occurred.

14. The Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

SO ORDERED this 14th day of March, 2023.

BOARD SEAL

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR
MISSOURI BOARD OF PHARMACY

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
9314 8699 0430 0105 6149 15

March 16, 2023

Michael Sanders, MIC
Alcon Vision LLC
6740 Business Pkwy
Elkridge, MD 21075

Dear Mr. Sanders:

Enclosed is a copy of the fully executed **ORDER OF THE MISSOURI BOARD OF PHARMACY ISSUING ALCON VISION, LLC A DRUG DISTRIBUTOR LICENSE SUBJECT TO PROBATION** and the Missouri drug distributor permit #2023009853. The Order is effective March 14, 2023.

Enclosed are two copies of our Pharmacy and Drug Distributor Report of Discipline Compliance form for use in submitting the six-month reports required by the Agreement. The first report will be due **July 1, 2023**, and each January and July following through the ending date of probation. This form may be copied as needed for future use, and is also available on our website at www.pr.mo.gov/pharmacists, click Applications and Forms, under Miscellaneous.

You should review each term of this Agreement and comply with the requirements as set forth. Compliance with this Agreement is your responsibility; reminders will not be sent from this office. Failure to comply with the terms of this Agreement may result in a violation hearing before the Board.

Sincerely,

Jennifer Boehm

JENNIFER BOEHM
ADMINISTRATIVE COORDINATOR

Enclosure

cc: Daryl Hylton, Attorney
David Endicott, CEO CERTIFIED MAIL TRACKING NO. 9314 8699 0430 0105 6149 60

BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI

IN RE:	)
	)
ALCON VISION, LLC	)
6740 Business Parkway	)
Elkridge, MD 21075	)

ORDER OF THE MISSOURI BOARD OF PHARMACY
ISSUING ALCON VISION, LLC.
A DRUG DISTRIBUTOR LICENSE
SUBJECT TO PROBATION

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug distributor license, license number 2023009853, to ALCON VISION LLC (Alcon) for its Elkridge site pursuant to the provisions of Section 324.038, RSMo. As set forth in Section 324.038, RSMo, Alcon may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to Alcon. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of Alcon's drug distributor license. Should Alcon file a written request

for review of this Order, the terms and conditions of the Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. Alcon filed an application for licensure as a drug distributor on or about December 21, 2022 for its Elkridge site. This location was previously licensed by the Board under Alcon Laboratories, Inc., but its license expired on October 31, 2019. The license issued pursuant to this Order is in response to the December 21, 2022 application.

3. During the period October 31, 2019 through November 28, 2022, Alcon distributed legend drugs or devices into Missouri from its Elkridge site on at least 270 occasions without holding an active Missouri drug distributor license for the site.

4. In addition, during this period, Alcon distributed legend drugs and devices into Missouri from additional unlicensed sites on over 25,000 occasions.

5. Section 338.333, RSMo prohibits acting as a drug distributor without first obtaining a license to do so from Missouri.

6. Sections 338.333 and 338.335, RSMo, requires licenses for each distribution site owned or operated by a wholesale drug distributor.

7. Alcon's conduct as alleged above is cause for the Board to deny Alcon licensure as a drug distributor pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:

1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of, or assisting or enabling ay person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

8. Section 324.038.1, RSMo, provides in pertinent part:

1. Whenever a board within or assigned to the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license,

may, at its discretion, issue to an applicant a license subject to probation.

ORDER

9. Based on the foregoing, it is the ORDER of the Missouri Board of Pharmacy that, in lieu of denying Alcon licensure as a drug distributor for its Elkridge site, the Board hereby issues Alcon drug distributor license number 2023009853 subject to PROBATION for a period of TWO YEARS. This Order shall become effective on the date issued. The terms of probation shall be:

A. Alcon shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

B. Alcon shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If, after disciplinary sanctions have been imposed, Alcon fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

D. Alcon shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

E. Alcon agrees that it will make itself available for

inspection by inspectors employed by the Missouri Board of Pharmacy between January 1 and December 31 of each year it is under discipline. This also includes the beginning and ending years of the discipline. The Respondent shall reimburse the Board for travel expenses and meals incurred to facilitate these inspections including, but not limited to, airfare, lodging, shuttle, and transportation expenses within seven (7) days of being provided a notice and valid receipts for said expenses. Travel expenses and meals shall be governed by the recognized Missouri Office of Administration guidelines for state employee travel.

F. Alcon shall make a representative available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Alcon will be notified and given sufficient time to arrange these meetings.

G. Alcon's failure to comply with any condition of discipline set forth herein constitutes a violation of this Order.

10. Upon the expiration of said probation, Alcon's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that Alcon has violated any term or condition of this Order, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Alcon

11. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

12. If the Board determines that Alcon has violated a term or condition of this Order, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Order occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Order has occurred.

13. The Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

SO ORDERED this 14th day of March, 2023.

BOARD SEAL

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR
MISSOURI BOARD OF PHARMACY

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year. Alcon Vision, LLC stores and distributes finished drug product manufactured by Alcon Research, LLC

Name: Alcon Research, LLC

Address: 6201 South Freeway City: Fort Worth State: TX Zip: 76134

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Alcon Laboratories, Inc.

Corporation/Organization Name: Alcon Vision, LLC

Mailing Address: 6201 South Freeway, Mail Stop R9-2

City: Fort Worth State: TX Zip: 76134

Telephone: [redacted] Email: [redacted]

Contact Person Name: Coy Mills

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓ N/A	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓ N/A	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Alcon Vision, LLC

Facility Name

Coy Mills

Print Name of Authorized Person Submitting Application

[redacted]

Original si[redacted]r stamps not accepted)

11.02.2023

Date

Board Use Only	Date Received: 11/13/23	Amount: $1000 - check 12194

Signature Delegation – Quality and Regulatory Affairs

Alcon

State Licenses

To: File
Date: January 3, 2023
Subject: Letter of Delegation - State Licenses

This serves to notify interested parties that David Endicott has delegated his signature authority for Alcon's state licensing projects to Coy Mills, Director, Regulatory Operations.

Coy Mills will engage in discussions with David Endicott on specific issues related to these projects as required.

This delegation of signature authority is limited in scope to the above, does not exclude his additional review and approval of documents at his discretion, and may be revoked by David Endicott at any time.

Delegated By (signature)

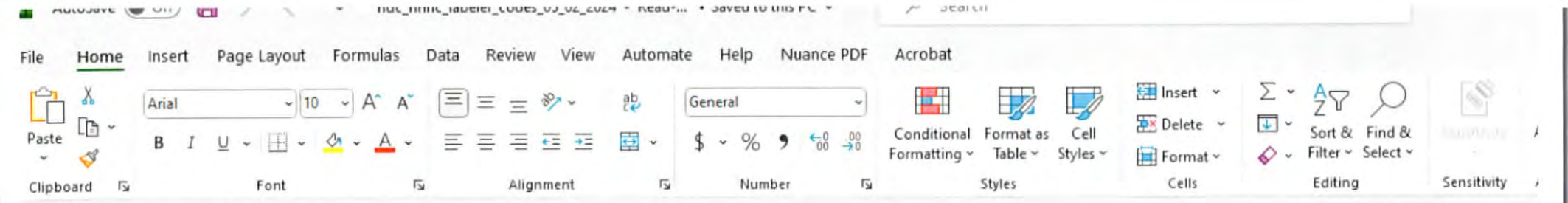
[redacted] 01/03/2023

David Endicott
Chief Executive Officer

Delegation Acknowledged By (signature)

[redacted] 01. 03. 2023

Coy Mills
Director, Regulatory Operations



NDC/NHRIC Labeler	Firm Name
72641	Tasman Pharma Inc.
74194	Pratt Energy, LLC
71504	Knet Systems Corp.
82977	EZ-LIFE PHARMACEUTICALS LLC
60345	Thomas Pawlowski/Thomas Respiratory Health Care
65376	Minteq U K LTD
77279	Seber Design Group, LLC
72985	Eye Essentials LLC
73743	Cleanpak Products, LLC
68841	John L Seaton & Co Ltd
71070	Balshi MD Dermaceuticals
13840	Nanyang Pukang Pharmaceutical Co., Ltd.
76885	Emergency Medical Solutions LLC
73302	HRA Pharma America, Inc.
54384	American Oxygen Company, Inc.
70727	Alcon Laboratories, Inc.
53209	Morning Star OTC
29043	Biozyme Gesellschaft fur Enzymtechnologie mbH
80548	DUGEL LLC
81802	Orphalan SA
73266	One Home Medical Equipment, LLC
42766	Sac Val Janitorial Sales & Service, Inc.

Verified
5/2/24 M.H

Alcon Vision, LLC
6601 Oak Grove Road, Suite 300
Fort Worth, TX, 76134

Alcon
SEE BRILLIANTLY

Corporate Officers

ALCON VISION, LLC OFFICER INFORMATION

David Endicott
Chief Executive Officer
Home Address: [redacted]

Sergio Duplan
President, North America
Home Address: [redacted]

Tim Stonesifer
Chief Financial Officer and Treasurer
Home Address: [redacted]

Alcon Vision, LLC
6601 Oak Grove Road, Suite 300
Fort Worth, TX, 76134

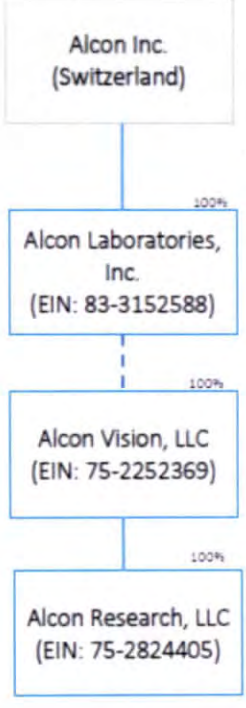
Alcon
SEE BRILLIANTLY

Entity Hierarchy

Entity Hierarchy

Alcon Vision, LLC was established in 2018 in preparation for Alcon's separation from Novartis AG to serve as the commercial sales entity within the United States. The FDA registered trade name for Alcon's prescription drug products is Alcon Laboratories, Inc., which Alcon Vision, LLC is a wholly owned subsidiary of. Also, as noted below, Alcon Inc. is the publicly traded entity, formed on April 9, 2019.

Entity Organization Chart



Alcon Inc. was formed on September 21, 2018 as a wholly owned subsidiary of Novartis AG. As of April 5, 2019, the transfer of all of the Novartis AG subsidiaries associated with the Alcon group to Alcon Inc. was completed. Alcon Inc. spun off from Novartis AG to become a separate, publicly traded company on April 9, 2019.

Formerly known as Alcon US Holdings Corporation
(Please note that this entity is a different and separate entity from the former Alcon Laboratories, Inc. which merged into Alcon Vision, LLC on February 28, 2019 and carries a different EIN.)

Formerly known as Alcon Laboratories, Inc.

Formerly known as Alcon Research, Ltd.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALCON VISION, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTH DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ALCON VISION, LLC" WAS FORMED ON THE FOURTH DAY OF DECEMBER, A.D. 2018.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7178807 8300

SR# 20241883967

Authentication: 203405821

Date: 05-06-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

August 08, 2023

A search of our records reveals the following information for the entity record selected.

Entity Name: Alcon Vision, LLC
Registered in Texas as: Alcon Vision, LLC
Entity Type: Foreign Limited Liability Company (LLC)
Jurisdiction: DELAWARE, USA
File Number: 803343979
Registered: June 13, 2019 Effective: June 13, 2019

The status of the entity is in existence.

The name and address of the registered agent and office in Texas is:

CORPORATION SERVICE COMPANY DBA CSC - LAWYERS INCORPORATING SERVICE COMPANY
211 E. 7TH STREET, SUITE 620
AUSTIN, TX 78701-3218
USA

The entity recorded the following assumed name(s) with this office:

The entity has not recorded any assumed name certificates with this office.

The management information from our computer records lists:

DAVID ENDICOTT PRESIDENT AND CEO	6201 SOUTH FREEWAY FORT WORTH, TX 76134 USA
LAURENT ATTIAS HEAD, GLOBAL COMMERCIAL STRATEGY	6201 SOUTH FREEWAY FORT WORTH, TX 76134 USA
HEATHER ATTRA SR. VP, HEAD GLOBAL QUALITY	6201 SOUTH FREEWAY FORT WORTH, TX 76134 USA
ROYCE RICHARD BEDWARD	6201 SOUTH FREEWAY

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

ALCON VISION LLC
6201 S FWY
FORT WORTH TX 76134

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

ALCON VISION LLC
6601 OAK GROVE RD STE 300
FORT WORTH, TX 76134

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1003648
Expires: March 22, 2025

NON-TRANSFERABLE

Commissioner

517029

TEXAS Department of State Health Services

License Number: 1003648 ***Current Date: 10/18/2023 10:06 AM***

Name:	**ALCON VISION LLC**
License Type:	**Prescription Drug Distributor**
License Status:	**Current**
Expiry Date:	**03/22/2025**
Effective Rank Date:	**06/23/2023**
Modifier(s):	**Wholesales Distributor**
	Non Prescript
	Prescription

Addresses

Physical Loc	Address	ALCON VISION LLC 6601 OAK GROVE RD STE 300 FORT WORTH , TX TARRANT 76134 US
Mailing Address	Address	ALCON VISION LLC FORT WORTH , TX TARRANT 76134 US

Food & Drug Owner

Licensee's Role:	**Food & Drug License**
Related Party Role:	**Food & Drug Owner**

Related Party Name	License	Address
ALCON VISION LLC	**Owner #A075748** Status: Current Expiration Date:	6201 S FWY FORT WORTH , TX TARRANT 76134 US

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

ALCON RESEARCH LLC
6201 S FWY MC R92
FORT WORTH TX 76134

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

ALCON VISION LLC

6601 OAK GROVE RD STE 300
FORT WORTH, TX 76134

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE DISTRIBUTOR

License # 1003123
Expires: October 19, 2024

NON-TRANSFERABLE

Commissioner

512767

TEXAS Department of State Health Services

License Number: 1003123 ***Current Date: 10/18/2023 10:05 AM***

Name:	**ALCON VISION LLC**
License Type:	**Dev Distributor**
License Status:	**Current**
Expiry Date:	**10/19/2024**
Effective Rank Date:	**11/23/2022**
Modifier(s):	**Distributor**
	Initial Distributor (Importer)
	Own Label Distributor
	Class 1
	Class 2
	Class 3
	Implantable
	Over-the-Counter
	Prescription
	Sterile-Packaged

Addresses

Mailing Address	Address	ALCON RESEARCH LLC FORT WORTH , TX TARRANT 76134 US
Physical Loc	Address	ALCON VISION LLC 6601 OAK GROVE RD STE 300 FORT WORTH , TX TARRANT 76134 US

Food & Drug Owner

Licensee's Role:	**Food & Drug License**
Related Party Role:	**Food & Drug Owner**

Related Party Name	License	Address
ALCON VISION LLC	Owner #A075748 Status: Current Expiration Date:	6201 S FWY FORT WORTH , TX TARRANT 76134 US

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 03/20/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Philadelphia PA Office 100 North 18th Street 15th Floor Philadelphia PA 19103 USA	PHONE (A/C. No. Ext): [redacted]	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Alcon Laboratories, Inc. and Ivantis, Inc. 6201 South Freeway Fort Worth TX 76134 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B: Federal Insurance Company	20281
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570104448410 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY			99507249	04/01/2024	04/01/2025	EACH OCCURRENCE	$5,000,000
	X CLAIMS-MADE ☐ OCCUR			SIR applies per policy terms & conditions			DAMAGE TO RENTED PREMISES (Ea occurrence)	$5,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$5,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$5,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 314682-24	04/02/2024	04/02/2025	COMBINED SINGLE LIMIT (Ea accident)	$5,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	
	☐ DED ☐ RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			MWC31468124	04/02/2024	04/02/2025	X PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/ PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N / A		AOS			E.L. EACH ACCIDENT	$5,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$5,000,000
							E.L. DISEASE-POLICY LIMIT	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Named Insured includes: Alcon Vision, LLC and Alcon Research, LLC.

CERTIFICATE HOLDER

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth TX 76134 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570104448410

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AGENCY CUSTOMER ID: 570000078957
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Alcon Laboratories, Inc.
POLICY NUMBER	
See Certificate Number: 570104448410	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570104448410	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

Alcon Laboratories, Inc.

Lessors of Premises

Person (other than your employees) or orgnizations from whom you leased premises are insureds; but they are insureds only if you are obligated (pursuant to a witten contractor or agreement between you and such person or organization) toprovide them with such insurance as is afforded by this policy.

However, such a person orgabization is an insured only:

* for such activities that did not occur after you cease to be a tenant in such premises.
* with respect to the ownership , maintance or use of that particular part of such premises leased to you
* to the extent such contract or agreement requires the person or organization to be aforded status as an insured.
*for such activities that did not ocur, in whole or in part, before the execution of the contract or agreement.

No person or organization is an insured under this provision with respect to any:

*assumption of liability(of another personor organization) by them in a contract or agreement. this limitation does not apply to the liability for damages for injury or damage, to which this insurance applies, that such person or organization would have in the absence of such contract agreement.
*structural alteration, new construction or demolition operations performed by or on behalf of them.

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AGENCY CUSTOMER ID: 570000078957

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Alcon Laboratories, Inc.
POLICY NUMBER	
See Certificate Number: 570104448410	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570104448410	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Alcon Laboratories, Inc.

Vendors
Persons (other than your employees) or organizations that are vendors of your product are insureds; but they are insureds only if you are obligated (pursuant to a contract or agreement) to provide them with such insurance as is afforded by this policy.
However, such a person or organization is an insured only:
- with respect to their liability for damages for bodily injury or property damage resulting from the distribution or sale of your product to which this insurance applies;
- to the extent such contact or agreement requires the person or organization to be afforded status as an insured; and
- for such activities that did not occur, in whole or in part, before the execution of the contract or agreement.

No person or organization is an insured under this provision with respect to any:
- assumption of liability (of another person or organization) by them in a contract or agreement. This limitation does not apply to the liability for damages for injury or damage, to which this insurance applies, that such person or organization would have in the absence of such contract or agreement.
- representation or warranty unauthorized by you.
- reckless or willful violation of any law or regulation.
- failure to make adjustments, inspections, services or tests that the person or organization has agreed to make or normally undertakes to make in the regular course of their business in connection with the distribution or sale of your product.
- chemical or physical change in your product made intentionally by the person or organization.
- repacking, unless unpacked solely for the purpose of demonstration, inspection or testing or the substitution of parts under instruction from the manufacturer and then repacked in the original container.

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AGENCY CUSTOMER ID: 570000078957
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Alcon Laboratories, Inc.
POLICY NUMBER: See Certificate Number: 570104448410	
CARRIER: See Certificate Number: 570104448410 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

Alcon Laboratories, Inc.

Vendors
- demonstration, installation, repair or servicing operations, except such operations performed at the person's organization's premises in connection with the distribution or sale of your product,
- of your products that, after distribution or sale by you, have been labeled or relabeled or used as a container, ingredient or part of any other substance or thing by or for the person or organization.

Further, no person or organization is an insured under this provision:
A. from whom you have acquired your product, or any container, ingredient or part accompanying, entering into or containing your product,
B. that is acting as a:
1. human clinical trial contractor;
2. life science product sales contractor; or
3. life science product service contractor

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VERIFICATION CERTIFICATE

BOND NO.: 019084025

EFFECTIVE DATE: December 28, 2022

SURETY: LIBERTY MUTUAL INSURANCE COMPANY

PRINCIPAL: ALCON VISION, LLC AND ALCON RESEARCH, LLC

OBLIGEE: NEVADA STATE BOARD OF PHARMACY

DESCRIPTION: All Facilities License

BOND AMOUNT: One Hundred Thousand Dollars ($100,000.00) Dollars

This is to certify that this company has not terminated its Suretyship under the above described bond and that such bond, according to its records, is still in force and effect and will continue in force and effect until cancelled per the terms set forth in the bond.

Signed and sealed this 29th day of May, 2024.

LIBERTY MUTUAL INSURANCE COMPANY

By: _____
Elizabeth P. Cervini, Attorney-in-Fact

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Seal No. 5865

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual. SURETY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8209978-019008

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Christine M. Hrusovsky; David A. Johnson; David C. Rosenberg; Denise M. Bruno; Elizabeth B. Pendleton; Elizabeth P. Cervini; Harry C. Rosenberg; James M. DiSciullo; John E. Rosenberg; Jonathan F. Black; Julia R. Burnet; Matthew J. Rosenberg; Melissa J. Hinde; Stephanie S. Helmig

all of the city of Wayne state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 19th day of April, 2023.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West Americen Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 19th day of April, 2023 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 29th day of May, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2023

Assets		Liabilities	
Cash and Bank Deposits	$1,850,245,073.00	Unearned Premiums	$10,298,963,305.00
*Bonds – U.S Government	$3,859,565,383.00	Reserve for Claims and Claims Expense	$28,848,537,243.00
*Other Bonds	$21,048,805,773.00	Funds Held Under Reinsurance Treaties	$360,714,151.00
*Stocks	$19,937,271,802.00	Reserve for Dividends to Policyholders	$1,310,198.00
Real Estate	$122,228,711.00	Additional Statutory Reserve	$296,126,000.00
Agents' Balances or Uncollected Premiums	$8,208,660,427.00	Reserve for Commissions, Taxes and Other Liabilities	$7,622,413,466.63
Accrued Interest and Rents	$186,906,667.00	**Total**	**$47,428,064,363.63**
Other Admitted Assets	$15,677,869,683.63	Special Surplus Funds	$209,508,757.00
Total Admitted Assets	**$70,891,553,519.63**	Capital Stock	$10,000,075.00
		Paid in Surplus	$13,834,867,488.00
		Unassigned Surplus	$9,409,112,836.00
		Surplus to Policyholders	$23,463,489,156.00
		Total Liabilities and Surplus	**$70,891,553,519.63**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2023, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2024.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 019084025

Application/License No. _____

Alcon Vision, LLC & Alcon Research, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 6201 South Freeway, Fort Worth, TX 76134 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1001 4th Avenue, Suite 1700, Seattle, WA 98154 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on December 28, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 28th day of December, 2022.

APPLICANT/PRINCIPAL

Alcon Vision, LLC & Alcon Research, LLC

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Liberty Mutual Insurance Company

Surety Company's Representative

John E. Rosenberg, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Kyle W. Koziol, Witness

Witness Jonathan F. Black, Witness

Countersigned by:

N/A
Nevada Resident Agent

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8207586-019008

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Christine M. Hrusovsky; David A. Johnson; David C. Rosenberg; Denise M. Bruno; Elizabeth P. Cervini; Harry C. Rosenberg; James M. DiSciullo; John E. Rosenberg; Jonathan F. Black; Joyce M. Houghton; Julia R. Burnet; Matthew J. Rosenberg; Melissa J. Hinde; Stephanie S. Helmig

all of the city of Wayne state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of April, 2022.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 1st day of April, 2022 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 28th day of December, 2022.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT — DECEMBER 31, 2021

Assets

Cash and Bank Deposits	$2,234,770,744
*Bonds — U.S Government	4,250,615,811
*Other Bonds	16,983,165,862
*Stocks	20,075,458,019
Real Estate	182,250,567
Agents' Balances or Uncollected Premiums	7,607,687,836
Accrued Interest and Rents	120,173,987
Other Admitted Assets	14,076,622,575
Total Admitted Assets	**$65,530,745,401**

Liabilities

Unearned Premiums		$9,106,965,847
Reserve for Claims and Claims Expense		25,279,158,493
Funds Held Under Reinsurance Treaties		315,537,902
Reserve for Dividends to Policyholders		1,726,291
Additional Statutory Reserve		139,634,000
Reserve for Commissions, Taxes and Other Liabilities		8,638,106,801
Total		**$43,481,129,334**
Special Surplus Funds	$178,192,363	
Capital Stock	10,000,075	
Paid in Surplus	11,804,736,755	
Unassigned Surplus	10,056,686,874	
Surplus to Policyholders		**22,049,616,067**
Total Liabilities and Surplus		**$65,530,745,401**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the state of Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2021, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2022.

T A Mikolajewski

Assistant Secretary

S-1262LMIC/a 3/22

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Alcon Vision, LLC MDEG License # (if applicable) _____

Physical Address 6601 Oak Grove Road Suite 300

City Fort Worth State TX Zip 76134

Mailing Address (if different from physical address) 6201 South Freeway, Mail Stop R9-2

City Fort Worth State TX Zip 76134

Telephone [redacted] Website www.alcon.com

Licensing Company Email [redacted]

Section 2: Personal Information

First Cody Middle O'Neill Last Hutson

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Godley State TX Zip 76044

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Texas Christian University		08/07-06/10	
Address	**City**	**State**	**Zip**
2800 South University Drive	Fort Worth	TX	76109
Diploma/Degree obtained, if any			
Communication Bachelors			

School Name		From - To (MM/YY – MM/YY)	
Northwestern College of Iowa		08/06-06/07	
Address	**City**	**State**	**Zip**
101 7th Street	Orange City	IA	51041
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Nolan Catholic High School		08/02-05/06	
Address	**City**	**State**	**Zip**
4501 Bridge Street	Fort Worth	TX	76103
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19 - Current	[redacted]	Godley	TX	76044
08/18 - 05/19		Fort Worth	TX	76123
09/14 - 08/18		Azle	TX	76020
11/10 - 09/14		Fort Worth	TX	76114
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Alcon Vision, LLC		10/16 - Present	
Business Address	**City**	**State**	**Zip**
6201 South Freeway	Fort Worth	TX	76134
Phone	**Title**	**Number of Employed Hours**	
817-293-0450	Assistant Distribution Manager	52,560	
Description of Duties			
Responsible for shipments from Alcon Distribution Center			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

ectronic, copies or stamps not accepted)

11/2/23
Date

I, Cody Hutson, **certify that as the MDEG Administrator for**

Alcon Vision, LLC,

that I (initial that you have read and meet the following requirements):

1. CH Have a high school diploma or its equivalent;
2. CH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cody Hutson

Print Name (First, Last)

[redacted]

onic, copies or stamps not accepted)

11/2/23

Date

Board Use Only	Date Received: 11/3/23

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Alcon Vision, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 6601 Oak Grove Rd Suite 300

City Fort Worth State TX Zip 76134

Mailing Address (if different from physical address) 6201 South Freeway, Mail Stop R9-2

City Fort Worth State TX Zip 76134

Telephon[redacted] Website www.alcon.com

Licensing Company Email [redacted]

Section 2: Personal Information

First Cody Middle O'Neill Last Hutson

Alias(es, nicknames, name changes, etc.) _____

Date of Birth[redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address[redacted]

City Godley State TX Zip 76044

Telephone[redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Texas Christian University		08/07 - 06/10	
Address	**City**	**State**	**Zip**
2800 South University Dr	Fort Worth	TX	76109
Diploma/Degree obtained, if any			
Communication Bachelors			

School Name		From - To (MM/YY – MM/YY)	
Northwestern College of Iowa		08/06 - 06/07	
Address	**City**	**State**	**Zip**
101 7th SW	Orange City	IA	51041
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Nolan Catholic High School		08/02 - 05/06	
Address	**City**	**State**	**Zip**
4501 Bridge St	Fort Worth	TX	76013
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19 - Current	[redacted]	Godley	TX	76044
08/18 - 05/19		Fort Worth	TX	76123
09/14 - 08/18		Azle	TX	76020
11/10 - 09/14		Fort Worth	TX	76114
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Alcon Vision LLC			10/16 - Present	
Business Address		**City**	**State**	**Zip**
6201 South Freeway		Fort Worth	TX	76134
Phone	**Title**		**Number of Employed Hours**	
817-293-0450	Assistant Distribution Manager		52,560	
Description of Duties				
Responsible for shipments from Alcon Distribution Center.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

10/26/23
Date

I, Cody Hutson, **certify that as the designated representative for**

Alcon Vision, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CH I am at least 21 years of age;
3. CH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Cody Hutson

[redacted]

Original Signature (faxed, emailed, copies or stamps not accepted)

10/26/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cody Hutson

Print Name (First, Last)

[redacted] 10/26/23

[redacted]nic, copies or stamps not accepted) Date

Please have this section completed in the presence of a Notary Public.

State of TEXAS, ss. County of TARRANT

I, Cody Hutson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted] 10/26/23

Original Signature **Date**

Subscribed and Sworn to before me this 26th day of OCTOBER.

Haley Murphy

Notary Public Signature

HALEY JOYCE MURPHY
Notary Public, State of Texas
Comm. Expires 11-13-2027
Notary ID 132259660

(Seal)

Alcon Vision, LLC
6601 Oak Grove Rd., Suite 300
Fort Worth, TX, 76134

Alcon
SEE BRILLIANTLY

Facility Employee / Contractor List

List of Employees and Contractors for 6601 Oak Grove Rd., Suite 300

Name	Position / Title
Daniel Copeland	Director, Distribution
Cody Hutson	Assist Mgr, Distribution Center
John Rogers Jr.	Supervisor, Distribution Center
Justin Miles	Assist Mgr, Distribution Center
Denise Boyt [C]	Direct Contingent Worker
James Bangiorno [C]	Direct Contingent Worker
Jerilyn Barnett	Distribution Center Operations Admin
Jimena Holgiun [C]	Direct Contingent Worker
Mustafa Ahmed [C]	Direct Contingent Worker
Natalie Amaya [C]	Direct Contingent Worker
Pedro Medina [C]	Direct Contingent Worker
Royce Hickman [C]	Direct Contingent Worker
Susan Maldonado	Distribution Center Operations Admin
Timothy Rabas [C]	Direct Contingent Worker
Tomasa Torres [C]	Direct Contingent Worker
Jonathan Sanchez	Supervisor, Distribution Center
Ruud Boijseauneau	Distribution Supervisor
Alejandro Adame Zambrano	Distribution Clerk 1
Allen Ortiz [C]	Direct Contingent Worker
Arthur Calton Jr.	Distribution Clerk II
Austin Goodman	Distribution Clerk I
Brian Gonzales	Distribution Clerk I
Catherine Gamez	Distribution Clerk I
David Rodela	Distribution Clerk II
Jesus Castorena	Distribution Coordinator
Jordynn Menchaca	Distribution Clerk I
Joseph Soto [C]	Direct Contingent Worker
Joseph Tovar	Distribution Clerk I
Jose Ynostrosa [C]	Direct Contingent Worker
Justin Campbell	Distribution Clerk 1
Lawrence Ramirez	Distribution Clerk
Leroy Epps	Distribution Clerk II
Linneth Arciniega	Distribution Clerk II

Alcon Vision, LLC
6601 Oak Grove Rd., Suite 300
Fort Worth, TX, 76134

Alcon
SEE BRILLIANTLY

Facility Employee / Contractor List

Lori Anders	Distribution Clerk 1
Luz Villegas Martinez	Distribution Clerk II
Mark Sanchez	Distribution Clerk I
Martin Garcia	Distribution Clerk I
Miguel Castorena	Distribution Clerk II
Mike Pool (On Leave)	Distribution Clerk II
Muliye Hart	Distribution Clerk I
Raquelin Rodriguez	Distribution Clerk I
Ray Thornton	Distribution Clerk II
Rowdy Chandler	Distribution Clerk II
Shaq Williams	Distribution Clerk I
Vanessa Torres [C]	Direct Contingent Worker
Jesus Palacios	Distribution Supervisor
Anthony Medrano	Distribution Clerk II
Brandon Edwards	Distribution Clerk II
Claude Simpson Jr	Distribution Clerk II
Clifford Price	Distribution Clerk II
Dulce Ramirez	Distribution Clerk I
Garrick Gardner [C]	Direct Contingent Worker
Gustavo Moreno	Distribution Clerk II
Howard Huntsberger	Distribution Coordinator
Jeffrey Holder	Distribution Clerk II
Jonathan Mew	Inventory Distribution Coordinator
Juan Delarosa	Distribution Clerk II
Mark Barr	Distribution Clerk II
Philip Engle	Inventory Distribution Coordinator
Raul Munoz	Inventory Distribution Coordinator
Shawn Dukes	Distribution Clerk II
alejandro ortiz	Distribution Clerk I
Cameron Smith	Distribution Clerk II
Carla Gonzalez	Distribution Clerk II
Christin Medrano	Distribution Clerk II
Christopher Quirino	Distribution Clerk II
Claudia Acosta	Distribution Clerk II
Connell Wickware [C]	Direct Contingent Worker

Alcon Vision, LLC
6601 Oak Grove Rd., Suite 300
Fort Worth, TX, 76134

Alcon
SEE BRILLIANTLY

Facility Employee / Contractor List

Danny Warren [C]	Direct Contingent Worker
David Alvarado	Distribution Clerk I
David Castorena	Warehouse Lead
Donniesha Daniels	Distribution Clerk I
Elizabeth Servin	Distribution Clerk I
Ernesto Reyes	Distribution Clerk II
German Trejo Munoz	Distribution Clerk I
hanna vincent	Distribution Clerk I
Jennifer Madrigal	Distribution Clerk II
Jennifer Stoner	Distribution Clerk I
Jordan Harper [C]	Direct Contingent Worker
Juan Rivas [C]	Direct Contingent Worker
Kurt Calvery	Distribution Clerk II
Linda Ma	Distribution Clerk I
Lizbeth Guzman	Distribution Clerk II
Lizett Guzman	Distribution Clerk II
Lynn Brown [C]	Direct Contingent Worker
Maria Ortega	Distribution Clerk I
Marisol Reyes	Distribution Clerk II
Maritza Reyna [C]	Direct Contingent Worker
Matthew Santana	Distribution Clerk I
Merly Perez [C]	Direct Contingent Worker
Nathaniel Flores [C]	Direct Contingent Worker
Nelson Mullings [C]	Direct Contingent Worker
Nicolas Gonzalez	Distribution Clerk I
Rafael Molina	Distribution Clerk I
Ramiro Hernandez	Distribution Clerk II
Reginald Johnson	Distribution Clerk II
Richard Harris	Distribution Clerk I
Robert Richeson [C]	Direct Contingent Worker
Sandra Garcia [C]	Direct Contingent Worker
Stacy Rizo [C]	Direct Contingent Worker
T.j. Stout	Distribution Clerk I
Toan Nguyen	Distribution Clerk II
Tyler Rotenberry [C]	Direct Contingent Worker

Alcon Vision, LLC
6601 Oak Grove Rd., Suite 300
Fort Worth, TX, 76134

Alcon
SEE BRILLIANTLY

Facility Employee / Contractor List

Vanesa Flores	Distribution Coordinator
Ana Garcia [C]	Direct Contingent Worker
Angela Huskins [C]	Direct Contingent Worker
Ashton Moore [C]	Direct Contingent Worker
Aurion Johnson [C]	Direct Contingent Worker
Brian Dark	Distribution Clerk II
Cesar De La Rosa	Distribution Clerk II
Curtis Waits [C]	Direct Contingent Worker
Danny Pridgeon	Distribution Coordinator
David Willis [C]	Direct Contingent Worker
Delores Hoffa	Distribution Clerk II
Elijah Cleveland [C]	Direct Contingent Worker
Emory Cleveland [C]	Direct Contingent Worker
Erica Watson [C]	Direct Contingent Worker
Gary Call	Distribution Clerk II
Huston Jerwan [C]	Direct Contingent Worker
Juan Mitchell	Distribution Clerk II
Kameron Williams	Distribution Clerk II
Lawrence Scottie [C]	Direct Contingent Worker
Martha Morales	Distribution Clerk II
Mirtha Paez	Distribution Clerk I
Myron Ross [C]	Direct Contingent Worker
Quincy Anitak [C]	Direct Contingent Worker
Reignna Clerkley	Distribution Clerk I
Sabastuan Allen [C]	Direct Contingent Worker
Stefani Edwards	Distribution Clerk I
Tristan Rush	Distribution Clerk II
Victor Quirino [C]	Direct Contingent Worker
Aaron Jones [C]	Direct Contingent Worker
Alma Avitia	Warehouse Associate
Andres Vargas	Distribution Clerk II
Ann Shockey	Distribution Clerk II
Brenda Bahr	Distribution Clerk II
Brian Gleason	Distribution Clerk 1
Danielle Davis	Distribution Clerk II

Alcon Vision, LLC
6601 Oak Grove Rd., Suite 300
Fort Worth, TX, 76134

Alcon
SEE BRILLIANTLY

Facility Employee / Contractor List

Derek Baker	Distribution Clerk II
Derryan Alexander	Distribution Clerk 1
DiAnthony Carpenter [C]	Direct Contingent Worker
Edson Parga	Distribution Coordinator
Francisco Vasquez	Distribution Clerk I
Jamesha Homer	Distribution Clerk II
Jayz Martinez	Distribution Clerk II
Jose Gutierrez-Romero	Distribution Clerk II
Joshua Dilday	Distribution Clerk I
Juan Castorena	Distribution Clerk II
Julian Dominguez	Distribution Clerk II
Karen Washington	Distribution Clerk II
Katherine Watson	Distribution Clerk II
Keion Walton [C]	Direct Contingent Worker
Luis Estrada [C]	Direct Contingent Worker
Maria Lozano	Distribution Clerk 1
Mario Lopez	Distribution Coordinator
Patricia Zapien	Distribution Clerk II
Quindarreyon Houzah [C]	Direct Contingent Worker
Rosalinda Mata [C]	Direct Contingent Worker
Rosario Ramirez	Distribution Clerk II
Ruth Benavides	Distribution Clerk 1
Srereeta Johnson [C]	Direct Contingent Worker
Steven Rodriguez	Distribution Clerk
Veronica Ortega	Distribution Clerk II
Victor Felix	Distribution Clerk 1

U.S. FOOD & DRUG ADMINISTRATION

Mr. Jason C. Michaelidies, Vice President, Post Market Quality
Alcon Research, LLC
Aspex Facility, 6201 South Freeway
Ft Worth, TX 76134-2099

Dear Mr. Michaelidies,

This letter informs you of the findings during the U.S. Food and Drug Administration (FDA) inspection conducted at your firm between September 12 and September 15, 2022. Investigator(s) Travis Beard and Habacuc Barrera, representing FDA, reviewed your postmarketing adverse drug experience (PADE) reporting program.

This inspection was conducted as a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of FDA-regulated research to ensure that the data, including PADE data, are scientifically valid and accurate, and to help ensure that the rights, safety, and welfare of the human subjects in the studies are protected.

We have reviewed the FDA Establishment Inspection Report and the documents submitted with the report. We conclude we did not identify any violations of the applicable statutory requirements or FDA regulations governing PADE requirements.

No response to this letter is necessary. If you have any questions or concerns about this letter or the inspection, please contact me by e-mail (CDER-OSI-ADE@fda.hhs.gov) or by letter at the address below.

Sincerely,

{See appended electronic signature page}

Carolyn Volpe, Pharm.D.
Team Lead
Pharmacovigilance Compliance Team
Postmarketing Safety Branch
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5306
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Alcon Research, LLC / Alcon Vision, LLC
6201 South Freeway
Fort Worth, TX, 76134

FDA Establishment Inspection Report – September 2022

Alcon
SEE BRILLIANTLY

To Whom it May Concern,

This notice has been drafted to explain the redactions observed within the attached establishment inspection report issued to Alcon Research, LLC (FEI 1610287) in February, 2023 for the audit conducted by the FDA in September, 2022.

The attached establishment inspection report was redacted by the FDA, not Alcon, and only includes redactions of the names of proprietary pharmaceutical product and / or molecules. The quality system elements that were inspected, as well as the overall outcome of the inspection, are not redacted.

Mills, Coy

Digitally signed by Mills, Coy
DN: cn=Mills, Coy, ou=PDF Internal Signing, o=Alcon Vision, LLC
Reason: I attest to the accuracy and integrity of this document
Date: 2023.02.23 08:35:17 -06'00'

Coy Mills – Director, Regulatory Operations / State Licensing

TABLE OF CONTENTS

Summary 1
Administrative Data 2
History 3
Interstate (I.S.) Commerce 3
Jurisdiction (Products Manufactured and/or Distributed) 3
Individual Responsibility and Persons Interviewed 3
Written Procedures 4
Source Data Extraction 5
Waivers 6
Follow-Up Information 6
Postmarketing Studies 6
[redacted] Trials Involving and Approved Drug Product 7
Pharmacovigilance Agreements And Safety Data Exchange Agreements 7
Corporate Transitions 7
Special Distribution Systems 8
Foreign PADE Reporting 8
PADE's Reported To The Firm's Legal Department 8
Scientific Literature Reports 8
Complaint Files 8
Periodic Safety Reports 9
[redacted] And [redacted] Annual Reports 9
PADE Reporting Requirements For OTC Monograph Drugs 9
Electronic Submissions 9
Part 11 Compliance 9
Refusals 9
General Discussion with Management 9
Voluntary Corrections 10
Exhibits Collected 10
Attachments 10

SUMMARY

This preannounced, routine surveillance, postmarketing adverse drug experience (PADE) inspection, FY22 (eNSpect Operation ID: 141314) issued by the Center for Drug Evaluation and Research

(CDER) was conducted in accordance with Compliance Program 7353.001 - Postmarketing Adverse Drug Experience Reporting Inspections. This is the 7th PADE inspection under this PAC. The previous PADE inspection was concluded on 05/23/2016 and classified as VAI with an Inspectional Observation for late submissions of postmarket periodic drug safety reports (PADERs).

The purpose of this current inspection was to verify the firm's compliance in PADE reporting activities and to review voluntary compliance corrective actions from the previous inspection. The current inspection consisted of a comprehensive review of the firm's post-marketing drug experience reporting which included the firm's written procedures for surveillance, receipt, evaluation, submission of PADE reports to the agency, submission of quarterly reports and annual periodic safety reports, event evaluation and coding, and trending/signaling of safety data.

The following products were selected for coverage: Isopto atropine, [redacted]; Cyclogyl 1%, [redacted]; Mydriacyl 1%, [redacted]; Fluorescein 10%, [redacted]; Pataday Once Daily Relief Extra Strength, [redacted]; Simbrinza [redacted]; and Systane Hydration, OTC Monograph. In addition, the following 2 products recently acquired by Alcon were reviewed to ensure FDA reporting requirements were properly completed: INVELTYS, [redacted] (approval date 08/22/2018); and EYSUVIS, [redacted] (approval date 10/26/2020).

I observed voluntary corrective action from the previous inspection. The firm implemented a monthly reporting to the Global Regulatory Group that documented any changes of the regulatory status of any product Alcon owned (drug approval status not timely identified was root cause of previous PADE inspection Observation). At the conclusion of the inspection on 09/15/2022, no FDA-483, Inspectional Observations was issued to the firm. No refusals were encountered during this inspection and no samples were collected.

ADMINISTRATIVE DATA

Inspected firm:	Alcon Research LLC
Location:	Aspex Facility, 6201 South Fwy Fort Worth, TX 76134-2099
Phone:	817-293-0450
FAX:	817-568-7170
Mailing address:	Aspex Facility, 6201 South Fwy Fort Worth, TX 76134-2099
Email address:	jason.michaelides@Alcon.com
Dates of inspection:	9/12/2022-9/15/2022
Days in the facility:	4
Participants:	**Travis M Beard, Investigator** **Habacuc V Barrera, Investigator**

This inspection was preannounced on 09/08/2022 to Jason C. Michaelides, Vice President, Post Market Quality with an agreed start date on 09/12/2022. On 09/12/2022, we presented our credentials and issued a "Form FDA 482, Notice of Inspection" (attached) to Jason C. Michaelides, Vice President, Post Market Quality'.

HISTORY

Since the previous PADE inspection the only changes to the firm has been the spin off from Novartis Corporation with Alcon now being a separate company solely owned by Alcon. This change assumed all PADE responsibilities to Alcon for their product list and the firm outsourced some of these responsibilities to IQVIA – **see the Corporate Transitions section of this report for more detail.**

All FDA Correspondence and (FMD-145) should be sent to:

Jason C. Michaelidies, Vice President, Post Market Quality
Alcon Research LLC
Aspex Facility, 6201 South Fwy
Fort Worth, TX 76134-2099
jason.michaelides@Alcon.com

INTERSTATE (I.S.) COMMERCE

There have been no changes to the firm's distribution of regulated products in interstate commerce since the last inspection.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

See **Exhibit** 1 for a list of the firm's regulated products and associated FDA application type and numbers.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Jason C. Michaelides, Vice President of Post Market Quality Alcon was present at the start of the inspection and the most responsible person. He has overall responsibility for end to end complaint management at Alcon that encompasses pharmacovigilance and device vigilance. Mr. Michaelides has been with Alcon for 20 years and reports to Heather Attra, Head Global Quality & Regulatory Affairs.

Meghan Graham, Director Pharmacovigilance Operations Alcon hosted the inspection and arranged interaction with various members of the company regarding the inspection. She also addressed PADE questions and hosted IQVIA personnel during the inspection. Ms. Graham has overall oversight of IQVIA for pharmacovigilance services. She has been with Alcon for 10 years and reports to Mr. Jason C. Michaelides, Vice President of Post Market Quality.

David B. Leers, Regional Director of Complaint Intake of the Americas Alcon discussed the complaint intake process at Alcon during the inspection and also navigated the itrack system for review of source data. He has been with Alcon for 5 years and reports to Mr. Jason C. Michaelides, Vice President of Post Market Quality.

Anna E. Martin, Associate Director of Complaint Intake of the Americas Alcon helped navigate the itrack system and provided information regarding the complaint system. She has been with Alcon for 5 years and reports to David B. Leers, Regional Director of Complaint Intake of the Americas.

Holly E. Adkins, Associate Safety Project Manager at IQVIA was present during the inspection to provided information regarding IQVIA services for Alcon and oversight. She reported to Meghan Graham, Director Pharmacovigilance Operations Alcon for these services that included multiple meetings throughout the month.

Manoj S. Pagare, Associate Manager Safety Operations at IQVIA discussed the case processing for individual case safety reports and also navigated the Argus system during case review for this inspection. He has been with IQVIA for 6 years and reports to Sujatha Krishnamoorphy, Manager of Safety Operations at IQVIA.

Kenneth Sullivan, PhD, Vice President Global Head of Clinical Alcon was present during the inspection and provided information regarding clinical trial studies and postmarketing activities. He has been with Alcon for 23 years and reports to Frank Leveiller, Sr. Vice President, Head Global R&D.

Bonita Wong, OD, Head of Medical and Safety Alcon was present during the inspection. She has overall oversight of the Alcon and IQVIA staff conducting medical review and signal detection. She has been with Alcon for 20 years and reports to Dr. Stephen Lane, Chief Medical Officer.

Chris Nguyen, Director of Quality Management, IQVIA provided information regarding data migration of the Safety Database following Alcon spin-off from Novartis. He has been with IQVIA for 8 years and reports to Eric Strauss, Global Head of Safety Technology.

WRITTEN PROCEDURES

Written procedures have been updated since the previous PADE inspection. These written procedures are accessible to all employees and documentation of training and review is recorded for employees. These procedures address the handling of data received during and outside of normal work hours through electronic, written, and telephone communications. The initial date information is received (the first encounter) is considered the aware date by the firm.

I observed the firm's written procedures to identify the four basic elements required for reporting,

and the employees to be trained on these procedures with this training documents in the firm's training system. The effective date of these written procedures at Alcon are dated after the split from Novartis in 2019. I also observed the written procedures to cover management of both spontaneous and study reports of adverse events, the expectedness, seriousness, coding, follow up information, and product complaints. The firm identifies potential adverse events based on patient harm (impact).

Alcon outsources some PADE activities to IQVIA that includes the following company and address: IQVIA RDS Inc., 4820 Emperor Boulevard, Durham, NC 27703; IQVIA Ltd., 3 Forbury Place, 23 Forbury Road, Reading, United Kingdom, RG1 3JH; and IQVIA RDS East Asia Pte Ltd., 79 Anson Road, #19-00, Singapore 079906. A copy of the Master Services Agreement and the Communication, Quality, and Safety plans are provided in **Exhibit 2**. The responsible person for each location is provided in the Agreement.

Written procedures for PADE reporting activities were collected for Alcon and IQVIA and are provided in **Exhibit 3** and **Exhibit 4** respectively.

The PADE responsibilities for Alcon and IQVIA are outlined below.

- Alcon: oversight of PADE process; intake of complaints and adverse events; follow-up of complaints and adverse events; aggregate reports submission; signal detection (safety management team and medical safety review board); safety label change and global labeling committee; local QPPVs (country specific); and pharmacovigilance agreements.

- IQVIA: individual case safety report (ICSR) case processing and medical review; global safety database (Argus){[IQVIA is responsible for maintaining this database] regulatory reporting; aggregate reports scheduling and writing; global and local literature search; pharmacovigilance system master file; signal detection; pharmacovigilance agreements support.

SOURCE DATA EXTRACTION

We reviewed written procedures for the management of both spontaneous and study adverse events. These procedures included the collection from studies, patient registries, patient support programs, and post market studies.

During the inspection, we reviewed approximately 10 Individual Case Safety Reports (ICSRs) per product, covering these reporting pathways to Alcon personnel. These ICSR's consisted of various ways in which adverse events were collected (market research, literature, call center, and patient support programs). No deficiencies were noted in the reportable information collected or the follow up activities.

Alcon's intake process would collect complaints (adverse events – determined by hardship to the

patient of person) including follow up information and enter this into their itrack system. The report generated from this system was then emailed to IQVIA for database entry into Argus, case processing (coding; case assessment; medical review) and reporting to the Health Authority.

The lead project manager for ICSRs performed by IQVIA was Holly Atkins, Project Manager at IQVIA.

We also reviewed 15-day alert reports reported late to FDA from 2019 to the present date during the inspection. The firm provided a copy of these late reports along with justification that is provided in **Exhibit 5**. The justifications consisted mostly of follow up interaction with Novartis following the separation in 2019. An example identified in the justifications were that Novartis sent adverse event information to Alcon's Regulatory email box and not the Safety email box from July to October 2019 that resulted in multiple late ICSRs. A copy of the Quality Issue Summary Report regarding these late ICSRs is provided in **Exhibit 6**.

Multiple Corrective and Preventative Actions (CAPAs) were reviewed for the products covered in the inspection to determine a common root cause and if correction was implemented and events not repeated. Mr. Michaelides informed us that Alcon did an audit of Novartis on 05/31/2022 to 07/07/2022 in response to the late ICSRs. He also informed us that the issue has not repeated since this event.

We reviewed the labels of the products reviewed during this inspection and compared them to the source data for accuracy in reporting. We also reviewed the firm's criteria in their written procedure for seriousness and coding. Alcon via IQVIA's written procedures does use the European Medicine Agency's Important Medical Event list for seriousness. The firm does have procedures written for consistent and accurate coding (MedDRA).

WAIVERS

No waivers were observed for the products reviewed.

FOLLOW-UP INFORMATION

We reviewed the firms written procedures and observed the documenting and reporting of follow-up information for adverse drug experiences. Instances where deviations occurred, CAPAs were created, and corrective actions were implemented appropriately.

POSTMARKETING STUDIES

Mr. Kenneth Sullivan informed us that for postmarketing studies the firm follows a Safety Management Plan for each study and the data entered into Veeva Systems Data Management and the vendor IQVIA assesses the seriousness and reports the adverse event accordingly to the Health Authority.

There were no active post market studies under an approved application for the time period reviewed during this inspection.

[redacted] TRIALS INVOLVING AND APPROVED DRUG PRODUCT

The firm did not have any [redacted] trials involving approved drug products for the time period reviewed in this inspection. We observed the firm had written procedures to address that collection of adverse events from [redacted] clinical trials that included the surveillance, receipt, evaluation, causality assessment, follow-up, and reporting of adverse event data. These steps are addressed in the study's management plan and includes the collection of the serious adverse events and the evaluation and processing of these through reporting.

PHARMACOVIGILANCE AGREEMENTS AND SAFETY DATA EXCHANGE AGREEMENTS

Alcon contracts PADE activities as indicated in the 'Written Procedures' section of this report to IQVIA. We reviewed contracts of vendors for the PADE reporting language and determined that it was adequate with regard to the firm's reporting activities. We also verified that the firm conducts audits of vendors and creates audit reports with follow-up to ensure corrective actions.

Mr. Michaelides informed us that following the Alcon spin off from Novartis in 2019 that each party had licenses that required transfer between the companies. He informed us that Simbrinza [redacted] was transferred to Alcon on September 2012 and that Novartis was required to send all US and Foreign case reports received to Alcon, and that Alcon was responsible for case submission and periodic adverse drug event reporting to the FDA.

Mr. Michaelides also informed us Kala Pharmaceuticals Inc. transferred the [redacted] for Eysuvis and Inveltys on August 31, 2022. He informed us Kala is responsible for sending complaints to Alcon and Alcon is responsible for the case processing, case submission, and periodic adverse drug experience reporting to the FDA.

IQVIA Alcon agreements are covered in the written procedures and throughout this inspection report.

CORPORATE TRANSITIONS

Alcon initiated agreements with IQVIA on 02/05/2019 to contract pharmacovigilance services. On 04/09/2019 Alcon completed the spin-off from Novartis and is now an independent and publicly traded company. In July 2019 transfer of pharmacovigilance activities from Novartis to Alcon began and multiple agreements were put in place to ensure Alcon oversight of activities and compliance.

Data Migration: After the split from Novartis, Alcon used IQVIA for managing the safety database and IQVIA has their own Argus Safety account. Chris Nguyen, Director of Quality Management,

IQVIA discussed the data migration after the separation of Alcon from Novartis. He informed us that there is a feature within Argus that allows the transfer of environment from company to company that has an account in Argus. He also provided the Alcon Validation Testing and Deployment Plan Reports (**Exhibit 7**; See Section 3 for details) and also provided the following significant dates regarding data migration from Novartis Argus to IQVIA Argus: Date of Extraction – 05/31/2019; Date of Reconciliation/Execution – 07/03/2019; and Date of Final Deployment – 08/12/2019.

Oversight: Ms. Graham has overall oversight of IQVIA for pharmacovigilance services and Ms. Bonita Wong, OD, Head of Medical and Safety has overall oversight of the Alcon and IQVIA staff conducting medical review and signal detection. Ms. Graham informed us that Alcon and IQVIA have multiple meeting throughout the month communicating upcoming reports, quality issues (deviations and CAPAs), These meetings included personnel from Regulatory, Safety, Quality, and Clinical. Ms. Graham informed us that these meetings covered timelines, content, draft review and feedback, quality control prior to forwarding to Global Regulatory for submission. We observed this practice and the Alcon's medical review oversight for signal detection via Ms. Wong's team.

SPECIAL DISTRIBUTION SYSTEMS

We reviewed written procedures for special distribution programs and information derived from these programs were confirmed to be collected as ADE's from postmarketing studies. Special distribution programs with the firm included patient support (patient access programs) and payment assistance (patient co-pay) programs. We informed that these programs handle adverse events were the intake written procedures that all Alcon employees follow for potential adverse event collection.

FOREIGN PADE REPORTING

Written procedures collected for PADE reporting cover both domestic and foreign reports.

PADE'S REPORTED TO THE FIRM'S LEGAL DEPARTMENT

The firm did not have any legal cases reported during the time period reviewed for this inspection. The firm's legal department is trained just as all Alcon employees are trained on adverse event intake collection and follow up. I observed the employees in the legal department to have documented training on these processes.

SCIENTIFIC LITERATURE REPORTS

The firm outsourced scientific literature review to IQVIA for Post Marketing Adverse Drug Experiences. During our review of ICSRs we observed literature cases and confirmed that all serious unexpected PADEs are reported in 15-day alerts and are accompanied with a copy of the source article.

COMPLAINT FILES

The firm treats all complaints that have patient harm as an adverse event. Product complaints related to device were not reviewed during this inspection.

PERIODIC SAFETY REPORTS

The firm submits quarterly and annual periodic reports for its approved products. We reviewed all periodic safety reports for the products reviewed and found that they were reported within the required time frames and met the required elements in the regulations. This category was involved in the FDA 483 Inspectional Observation from the previous PADE inspection – **See the Voluntary Correction section of this report.**

[redacted] AND [redacted] ANNUAL REPORTS

We verified that all [redacted] submissions were within the required time frame and confirmed that the anniversary date was the approval date for the application.

PADE REPORTING REQUIREMENTS FOR OTC MONOGRAPH DRUGS

We reviewed the OTC monograph drug Systane Hydration and observed the form reported all serious adverse events via electronic submission. No deviations were observed.

ELECTRONIC SUBMISSIONS

The firm is voluntarily participating with the agency's program to provide postmarketing regulatory submissions in electronic format.

PART 11 COMPLIANCE

We reviewed standard operating procedures (SOPs) and work instructions which indicate that the firm is part 11 compliant. No deficiencies were noted. We observed audit trails with usernames to identify the personnel creating the entry or change within the Argus and itrack system (The firm's adverse event intake entry system; Global Product Complaint Management System).

The firm does not have any AI algorithms related to pharmacovigilance reporting.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

Discussion with management occurred throughout the inspection. The general discussion with management was limited to information obtained during the conduct of this inspection. On 09/14/2022 a close-out meeting was held with Mr. Jason C. Michaelides, Vice President of Post Market Quality. No Form FDA 483 was issued at this closeout meeting. During the close-out meeting, We discussed the records reviewed during this inspection with the firm and asked if they had any questions. We informed Mr. Jason C. Michaelides, that upon further review, the conditions listed in this report may be deemed to be violations of the FDC Act or other legal statutes, and that the final determination of compliance will be made by CDER. With no further questions, we thanked Mr. Jason C. Michaelides for his time and assistance and the inspection was closed.

VOLUNTARY CORRECTIONS

We observed the firm did not repeat observations from the previous PADE inspection. The firm implemented a monthly reporting to the Global Regulatory Group that documented any changes of the regulatory status of any Alcon product owned. This monthly review ensured that any status changes like the drug approval (Novartis communicating a drug approval to Alcon) that resulted in late reporting to the FDA in the last PADE inspection would not be repeated. We observed meetings covering this topic and meeting minutes documenting discussion during this inspection.

EXHIBITS COLLECTED

1 Product List, 9 pages
2 Alcon IQVIA Master Service Agreement and Plans, 255 pages
3 Alcon Intake Written Procedures, 29 pages
4 IQVIA Written Procedures, 251 pages
5 15 Day Late Reports Justification, 1 page
6 Alcon Quality Issue Summary, 9 pages
7 Validation Testing and Deployment Plan Reports, 83 pages

ATTACHMENTS

1 FDA 482, Notice Of Inspection, 3 pages
2 Assignment Memorandum, 9 pages

Travis Beard -S
Digitally signed by Travis Beard -S
Date: 2022.09.30 13:51:15 -05'00'

Habacuc V. Barrera -S
Digitally signed by Habacuc V. Barrera -S
Date: 2022.09.30 14:16:29 -05'00'

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: AZURITY PHARMACEUTICALS, INC.

Physical Address: 8 CABOT ROAD, SUITE 2000

City: WOBURN State: MA Zip: 01801

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 781-935-8141 Website: WWW.AZURITY.COM

Name of Designated Representative (DR): HANOK GEORGE

Licensing Company Email: LICENSING@AZURITY.COM DR Email: HGEORGE@AZURITY.COM

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: VIRTUAL

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: SEE ATTACHED.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DELAWARE

Parent Company (if any): CUTISPHARMA INTERMEDIATE HOLDINGS, INC.

Corporation/Organization Name: AZURITY PHARMACEUTICALS, INC.

Mailing Address: 8 CABOT ROAD, SUITE 2000

City: WOBURN State: MA Zip: 01801

Telephone: 781-935-8141 Email: LICENSING@AZURITY.COM

Contact Person Name: HANOK GEORGE

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

AZURITY PHARMACEUTICALS, INC.

Facility Name

HANOK GEORGE

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4/10/2024

Date

Board Use Only	Date Received: 6/10/24	Amount: $1000-CK#529183

An official website of the United States government Here's how you know

FDA

Share Tweet Linkedin Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *Azurity Pharmaceuticals*

Showing 1 to 1 of 1 entries (filtered from 3 total entries)

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Azurity Pharmaceuticals, Inc.	3003395329	117505635	ANALYSIS	8 Cabot Road, Suite 3000, Woburn, Massachusetts (MA) 01801, United States (USA)	12/31/2024

Previous 1 Next

Data Current Through: Thursday, Jun 13, 2024

New Search

Azurity Pharmaceuticals, Inc.

Owners:

- CutisPharma Intermediate Holdings, Inc.
- 8 Cabot Road, Suite 2000, Woburn, MA 01801
- 100% Owner

Directors:

- Jeff Edwards
- Vern Davenport

Corporate Officers:

- President:
  - Richard Blackburn
  - 8 Cabot Road, Suite 2000, Woburn, MA 01801
  - (781) 281-3310
  - richard.blackburn@azurity.com
- Vice President:
  - N/A
- Secretary:
  - Hanok George
  - 8 Cabot Road, Suite 2000, Woburn, MA 01801
  - (781) 281-3286
  - hgeorge@azurity.com
- Treasurer:
  - Ronald Scarboro
  - 900 Ridgefield Drive, Suite 200, Raleigh, NC 27609
  - (984) 222-6817 Ext. 175
  - rscarboro@azurity.com

Description of Operations

Azurity Pharmaceuticals, Inc., located at 8 Cabot Road, Suite 2000, Woburn, MA 01801, is a virtual manufacturer that uses contract manufacturers to make branded drug products and a third-party logistics provider for all storage and distribution. We do not take physical possession of drug products under any circumstances. The office is open Monday through Friday from 8:30 a.m. to 5:00 p.m.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AZURITY PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF APRIL, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2977052 8300

SR# 20241264332

Authentication: 203159396

Date: 04-02-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Azurity Pharmaceuticals, Inc.
8 Cabot Road, Suite 2000
Woburn, MA 01801

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200095

Type: Virtual Manufacturer

Issue Date: 03/25/2024

Expiration Date: 03/25/2025

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

Inspection Report Statement

Azurity Pharmaceuticals, Inc., located at 8 Cabot Road, Suite 2000, Woburn, MA 01801, is licensed as a virtual manufacturer under the license number VIR200095 with the Massachusetts Controlled Substances Registration. This agency does not require virtual manufacturers to be inspected.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0229965	05-31-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	05-15-2023

CARDINAL HEALTH
DBA SPECIALTY PHARMACEUTICAL SERVICES
15 INGRAM BLVD
LA VERGNE, TN 370863630

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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Form DEA-223 (9/2016)

THE HARTFORD

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy STE 206
Reno, NV 89521

RIDER

Attached to and forming part of Bond # 83BSBIW5534 ,
on behalf of Azurity Pharmaceuticals, Inc.
of 8 Cabot Road, Suite 2000, Woburn, MA 01801
in favor of Nevada State Board of Pharmacy
and in the amount of Twenty-Five Thousand ($25,000.00) Dollars.

It is understood and agreed that effective April 11, 2024
The Bond Amount shall be changed
from $25,000
to $100,000

All other conditions and terms re main as originally written.

Signed, Sealed, and Dated April, 11th , 2024

Hartford Fire Insurance Company

By: _____

Christopher P. Troha , Attorney-in-Fact

The above rider is hereby agreed to and accepted:

By: _____

Form GENCNG (Rev. 0701/22)

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK SERVICES CENTRAL INC
Agency Code: 83-553702

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint Christopher P. Troha

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:

Bond No. 83BSBIW5534

Naming Azurity Pharmaceuticals, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,

in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of April 11, 2024.

Signed and sealed in Lake Mary, Florida.

Keith Dozois

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler AZURITY PHARMACEUTICALS, INC.
Pharmacy/Wholesaler License # (if applicable) _____
Physical Address 8 CABOT RD STE 2000
City WOBURN State MA Zip 01801
Mailing Address (if different from physical address) _____
City _____ State _____ Zip _____
Telephone 781-935-8141 Website WWW.AZURITY.COM
Licensing Company Email LICENSING@AZURITY.COM

Section 2: Personal Information

First HANOK Middle MATHEW Last GEORGE
Alias(es, nicknames, name changes, etc.) "GEORGE"
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X
Mailing Address 8 CABOT RD STE 2000
City WOBURN State MA Zip 01801
Telephone [redacted] Email LICENSING@AZURITY.COM
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ST MARY'S HIGH SCHOOL		08/01 - 05/05	
Address	**City**	**State**	**Zip**
27 BARTLETT ST	WESTFIELD	MA	01085
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
SIENA COLLEGE		08/05 - 05/09	
Address	**City**	**State**	**Zip**
515 LOUDON RD	LOUDONVILLE	NY	12211
Diploma/Degree obtained, if any			
BACHELOR OF ARTS			

School Name		From - To (MM/YY – MM/YY)	
ALBANY LAW SCHOOL OF UNION UNIVERSITY		08/09 - 05/12	
Address	**City**	**State**	**Zip**
80 NEW SCOTLAND AVE	ALBANY	NY	12208
Diploma/Degree obtained, if any			
JURIS DOCTOR			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/21 - CURRENT	[redacted]RATTLESNAKE HILL RD	ANDOVER	MA	01801
10/19 - 5/21	[redacted]FERGUSON RD APT 2	MALDEN	MA	02148
08/17 - 10/19	[redacted]BRAINARD AVE	MEDFORD	MA	02155
10/15 - 8/17	[redacted] DORCHESTER AVE	BOSTON	MA	02125
9/12 - 10/15	[redacted]RUNDEL PARK	ROCHESTER	NY	14607
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
AZURITY PHARMACEUTICALS, INC.			10/18 - CURRENT	
Business Address		**City**	**State**	**Zip**
8 CABOT RD STE 2000		WOBURN	MA	01801
Phone	**Title**		**Number of Employed Hours**	
781-935-8141	CHIEF LEGAL AND COMPLIANCE OFFICER		6000+ HOURS	
Description of Duties				
SERVES ON THE EXECUTIVE LEADERSHIP TEAM OF THE ORGANIZATION AND AS THE COMPANY SECRETARY. HE OVERSEES ALL ASPECTS OF THE LEGAL AND COMPLIANCE FUNCTIONS OF THE COMPANY.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/4/2024
Date

I, HANOK MATHEW GEORGE, **certify that as the designated representative for**

AZURITY PHARMACEUTICALS, INC.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HG I am at least 21 years of age;
3. HG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

HANOK GEORGE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/04/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hanok George

Print Name (~~First~~, Last)

Original Signature (electronic, copies or stamps not accepted)

6/4/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Middlesex

I, Hanok George, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/4/2024

Date

Subscribed and Sworn to before me this 4th day of June, 2024.

Notary Public Signature

Jared Tanz
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
March 25, 2027

(Seal)

Abdelfattah Sakhi
Abigail Wexler
Adam Mellen
Adel Gomez
Adren Hughes
Adrianna Loback
Ajay Singh
Alex Nunez
Alexandria Lopresto
Alisa Nguyen
Alison Leuven
Amanda Roden
Amber Kepley
Amit Lamba
Amit Patel
Amy Inthongkham
Ana Rivas
Anamalia Valandro
Andrea Struble
Andrew Ochenduszko
Anne Davis
Ashley Irvine
Ashley Nevelle
Ashley Smith
Audra Sneed
Autumn Merritt
Brandon Tutty
Brandon Whitaker
Brandon Whitman
Brian Runge
Brian Tabor
Brianna Irvine
Brianna Long
Britt Westmacott
Bryan Stewart
Cam Phung
Carmen Mejia
Carol Vuceta
Catherine Yeh
Cenia Peters
Charles Irvine
Cheyenne Sang
Chhoun Peth
Christina Williams
Christine Maurer
Christine Valway
Creighton Miller
Cristiane Rachid
Crystal Rosser
Daniel Zonderman
Darin Mast
Darryl Toquinto
David Goerz
David Miles
David Seaback

David Sequeira
Denver Tucker
Donna Wilmoth
Edward Helldorfer
Elena Shamshurina
Emma Hutchinson
Eric Greenberg
Erica Johnson
Erik Sockman
Erika Lang
Erin Poole
Etjen Nako
Eva Castellanos
Evan Scullin
Francis Tran
Francisco Lozano
Frank Zubal
Frantz Noel
Gary Hopkins
Gary Palmisano
Gayla Roberts
George Greene
George Schaible
Gerold Mosher
Gillian Miller
Gina Rogers
Glen Santy
Glen Silva
Golden Smith
Gregory Mar
Gyan Singh
Henry White
Hongsyn Keath
Hui Sheng
Inthalay Von
Jack Wilson
James Harn
James Tremblay
James Wu
Jane Stefiuk
Jared Tanz
Jason Harvard
Jason Hatley
Jason Herra
Jeffery Hughes
Jeffrey Roth
Jenifer Tuttle
Jennifer Mcginty
Jennifer Spangler
Jennine Hanaway
Jeremy Pyper
Jerica Rodriguez
Jie Liew
Joel Vega-Rodriguez
John Hall

John Mcnerney
John Ororke
John Peruzzi
John Walkowski
Jonathan Resendes
Jonathan Wilson
Jordan Hunt
Jordan Hunter
Jose Miller
Joseph Sturgeon
Joseph Tinnirella
Josh Matthew
Julie Marshall
Jun Liu
Justin Kilby
Katherine Pereira
Kathleen Kelly
Kelechi Obilor
Kellen Scarboro
Kelsey Phinney
Kelsey Steele
Kennedy Shasteen
Kevin Lapierre
Kevin Nem
Kevin Ortiz
Kimberly Raposo
Kimberly Robb
Kimberly Viens
Korie Osborn
Krista Tucker
Kristen Moore
Kristen Reilly
Kristen Totten
Kyle Parker
Lakaya Williams
Larry Pen
Laura Schuurman
Lauren Liese
Lauren Whitehead
Lavanya Lingala
Laxmitej Vengala
Leilani Hall
Lindsey Lane
Lindsey Reeves
Lisa Sheehan
Louis Pearce
Louis Riccio
Lucia Wang
Madison Leone
Mahendra Gunjal
Maiuridilaxshini Krishanthan
Marcos Hernandez
Maria Morabito
Mark Richardson
Mark Sander

Mark Schumacher
Marllelin Roman
Mary Polanco
Matthew Morgeson
Matthew Peranelli
Maulik Panchal
Mauro Rodrigues
Megan Mead
Meredith Knaak
Michael Hartman
Michael Moran
Michelle Reiter
Mitchel Greene
Morgan Loy
Naina Kataria
Narinder Singh
Nate Paulin
Nathan Walten
Nathaniel Vince
Nick Pham
Nicole Hengst
Nicole Vega
Niravkumar Sevak
Noah Rand
Orlando Mulero
Pamela Storey
Pamela Taylor
Paul Murasko
Jean Monroe
Peter Greene
Philisha Mack
Phillip Shilling
Phoebe Tran
Prathees Thiru
Praveen Subbappa
Rafaelina Ruiz
Rashad Rahman
Jody Rollins
Rebeca Aburto
Rhonda Vann
Rhorian Moss
Robert Yee
Rollin Knecht
Ronald Scarboro
Rossy Polanco
Rushil Shah
Ryan Mckay
Ryan O'Hearn
Samantha Valdiserri
Samir Patra
Samuel Schmidt
Sara Panzeri
Savannah Veal
Sean Lloyd
Sean Silveira

Seham Yennes
Sergio Gomes
Seth Goodman
Shane Gula
Shayista Syed
Sheri Mcgregor
Katie Mcmanus
Sophally Som
Sophear Pheang
Sophia Massey
Melody Mcdowell
Stacy Lewis
Suellen Zakos
Surya Kovvasu
Susan Monahan
Susmitha Palakurthy
Taeyeon Kim
Tammie Stapleton
Taylor Salinardi
Terrence Terifay
Thalita Paffenback
Michelle Klovanish
Thomas Sherr
Thrimoorthy Potta
Tia Long
Timothy Phillips
Timothy Ryan
Timothy Sefcik
Timothy Shadle
Timothy Vesci
Tristan Stritzel
Tyler Smith
Usha Roy
Thomas Knight
Vaishnavi Kasani
Vasiliki Weiden
Venus Taylor
Vijayaruban Vijayamohan
Vincent Rocco
Vishawavijay Singh
Wagner Ruane
Walter Klaus
Wendy Sullivan
Yatin Manchal
Yirandy Sanchez
Yiriana Reyes
Yiru Xu
Zeus Pendon
Devante Busby
Richard Horvath
David Prigmore
Lail Whittemore
Rupesh Chintamanibatla
Nidhi Patel
Daniel Lavan

Ali Nikkhah
Morgan Celestin
Cheryl Cornell
Hannah Czarnecki
Michael Dimaggio
Carrie
Shannon Fox
Amy Hagler
Rocky Nunley
Nicole Piacentini
Kayla Shafer
Connie Zann
Nikolay Pertesis
Abul Alam
Akash Gangrade
Alexis Evolga
Allula Reddy
Alvis Fields
Amanda Darwiche
Amanda Fincher
Amit Mishra
Amol Bhagat
Amy Eaton
Ananya Saha
Andre Ajayi
Andrew Bigham
Anushri Urunkar
Art Compean
Ashish Dubewar
Ashley Knotts
Athina Padmaja
Ayyagala Bhaskar
Badhavath Raju
Balakrishna Reddy
Balakrishna Sandha
Battini Somashekhar
Beau Bradley
Bella Almazan
Bharathi Devarakonda
Brandon Broussard
Breanna Beagley
Breanna Froemke
Brittany Allen
Bysani Kumar
Celeste Courville
Chegondi Kumar
Chieh Chou
Christi Bruns
Christian Coney
Karumuri Nagaraju
Ciara Boucher
Claire Evinson
Connor Adamik
Cooper Bigelow
Crystal Deleon

Danilo Chan
David Chesbro
David Dodge
Dawn Alexander
Naresh Isukapalli
Devaraju A
Dipen Desai
Divya Vulli
Donthu Kumar
Dorina Diekjuergen
Edward Buckley
Edwin Checo
Ekke Ramesh
Elizabeth Elder
Elizabeth Farris
Elizabeth Flynn
Pavan Kumar
Emily Carpio
Enid Curevac
Eric Blum
Eric Burge
Erika Santos
Fedoua Elhilali
Fenella Chisholm
Francisco Bonifacio
Gina Fallon
Giscard Beauvil
Gustavo Abreu
Hadeel Cirone
Haja Bangura
Hanaa Dembri
Hanimi Bapatu
Hanok George
Harish Chinnari
Harish Gunda
Harish Mangalagiri
Harold Fonseca-Mendez
Henry Chong
Iree Blount-Peterson
Jagdish Lohar
Jaimee Brooks
James Corbitt
Jason Boho
Jean Francois
Ravi Kumar
Jennifer Crosswell
Jesse Drake
Jesse Godsey
Jessica Fisher
Shiva Pindi
John Border
John Fanaras
Jonathan Beckloff
Joshua Burch
Julie Kimelman

Kaka Fofana
Kancheti Raghadev
Kara Cox
Sridher Ravula
V Suresh
Keerthi Priya
Keesara Reddy
Ketha Prasad
Kevin Flinn
Kimberly Deacon
Kirk Dumont
Kishore Kumar
Krishna Mohan
Kumar Swamy
Kunchapu Maruthi
Kylie Cusato
Lamartrus Exley
Laura Devries
Laura Fritts
Lekkala Chandra
Lena Cavallo
Lesly Alcius
Lisa Carroll
Lisa Davis
Lisa Kaczmarski
Lourdu Chinnu
Madan Rao
Madhusudhan Lachhannagari
Madison Garvey
Mahadeo Mahadik
Mahesh Vangara
Mallikarjun Patil
Mamidi Shankeraiah
Manikandan S
Mansing Patil
Manyam Harini
Marvin Choz
Mayur Adhav
Meghan Daggett
Christine Carbone
Michael Allen
Michael Beckloff
Michael Cecil
Michael Dibenedetto
Michael Dunn
Michael Gitomer
Michelle Fiordalisi
Debra Fangman
Michelle Fotso
Mohith Kota
Molugu Reddy
Mukkapati Rao
Nanette Almeida
Narayana Reddy
Natasha Abreu

Nichole Johnson
Palakurthi Venkatesh
Paleti Yamini
Pankaj Chatki
Paras Jain
Parvateesam Yenda
Paul Kan
Phuong Do
Pradeep Kare
Pramod Prashuramkar
Prem Singh
Premal Gandhi
Purushottam Pattewar
Rachel Berry
Ragavender Rao
Rahul Bhise
Raimonds Dzelme
Raj A
Rajesh Koduri
Ramesh Sandu
Randy Collins
Rathny Chep
Ravindhar Gonti
Ricardo Carmona
Richard Blackburn
Riley Fritze
Riya Bhagat
Robert Culhane
Robert Doherty
Robert Dullea
Rocio Delgado-Rocha
Rod Jose
Roxane Bradley
Royyuru Ramana
Ruben Berrios
Rupesh Atnure
Rykelle Boldt
Salisia Butler
Sally Alberg
Samuel Colon
Sandeep Jain
Sandeep Kumar
Sandhya Rani
Sandra Blanchet
Sarah Beggan
Saroeurn Chea
Sateesh Ambati
Satheesh Balasubramanian
Scott Brauer
Scott D'Zurilla
Scott Koon
Sean Dignan
Sean Fischer
Sharilynne Cline
Sheila Bhattacharya

Shelendra Bhati
Shweta Agarwal
Shyam Kumar
Sigamala Mallikarjuna
Siny John
Solla Vinod
Somnath Navgire
Sonia Kamath
Sowmen Porel
Srikanth Pinapla
Srinivasarao Kodela
Srinubabu Vasamsetti
Stacey Collins
Stephanie Behrens
Stephen Carbone
Sumitra Pillai
Susan Cramer
Sushant Dube
Swati Modi
Syed Arif
T Kumar
Tenisha Barnes
Tia Blount
Trenton Branstetter
Tumpati Ravindra
Udaya Bhaskar
Umangi Harikeerthi
Umesh Kulkarni
Valerie Johnson
Vanessa Eng
Veera Babu
Venkata Babu
Venkatesh Boga
Vijayender Reddy
Vinod Kothakota
Vinod Kumar
Vivian Chen
Walter Kallaher
David Lord
Michelle Fater
Kelly Dingle
Tucker Pena
Kevin Needle
Mairin O'Malley

CONTRACT MANUFACTURERS: PAGES 1-2

PACKAGERS: PAGE 3

THIRD-PARTY LOGISITICS PROVIDERS: PAGE 4

CONTRACT MANUFACTURERS

- AZURITY PHARMACEUTICALS, INC.
  - 841 WOBURN STREET, WILMINGTON, MA 01887
  - FEI: 3003395329
- ADARE PHARMA SOLUTIONS (CS-II)
  - 845 CENTER DRIVE, VANDALIA, OH 45377
  - FEI: 1525864
- MIKART, LLC (CS-II)
  - 1750 CHATTAHOOCHEE AVENUE NW, ATLANTA, GA 30318
  - FEI: 030034847
- GCP LABORATORIES
  - 3600 25TH AVENUE, GULFPORT, MS 39501
  - FEI: 965480861
- TAKEDA IRELAND LIMITED
  - GRANGE CASTLE BUSINESS PARK, DUBLIN, CO DUBLIN D22 XR57, IRELAND (IRL)
  - FEI: 3006687027
- DPT LABORATORIES LIMITED
  - 307 E. JOSEPHINE STREET, SAN ANTONIO, TX 78215
  - FEI: 1628114
- TULEX PHARMACEUTICALS, INC.
  - 5 CEDARBROOK DRIVE, CRANBURY, NJ 08512
  - FEI: 3011875665
- FERNDALE LABORATORIES, INC.
  - 780 W 8 MILE ROAD, FERNDALE, MI 48220
  - FEI: 1811212
- EISAI, INC.
  - 11675 Crossroads Circle, Baltimore, MD 21220
  - FEI: 1000158705
- PATHEON PHARMACEUTICALS, INC.
  - 2110 E GALBRAITH ROAD, CINCINNATI, OH 45237
  - FEI: 1510437
- KAVIS PHARMA, LLC
  - 12720 DAIR ASHFORD ROAD, SUGAR LAND, TX 77459
  - FEI: 1610608
- DELPHARM MONTREAL, INC.
  - 3535 AUT TRANSCANADIENNE, POINTE-CLAIRE, QC H9R 1B4, CANADA (CAN)
  - FEI: 3002808099

- PATHEON, INC.
    - 111 CONSUMERS DRIVE, WHITBY, ONTARIO L5N 7K9, CANADA (CAN)
    - FEI: 3003516812
- GALENICA S.A.
    - 3RD KM OLD NATIONAL ROAD CHALKIDA ATHENS, CHALCIS, 34100, GREECE (GRC)
    - FEI: 3012189222
- DEBIOPHARM RESEARCH & MANUFACTURING S.A.
    - RUE DU LEVANT 146, MARTIGNY, VS 1920, SWITZERLAND (CHE)
    - FEI: 3002806850
- PHARMACEUTICS INTERNATIONAL, INC.
    - 10819 GILROY ROAD, HUNT VALLEY, MD 21030
    - FEI: 1000513101
- LM MANUFACTURING LIMITED
    - CAVALRY HILL INDUSTRIAL AREA, NORTHAMPTON, NN7 4PP, UNITED KINGDOM
    - FEI: 3015337531

PACKAGERS

- AZURITY PHARMACEUTICALS INC.
  - 841 WOBURN STREET, WILMINGTON, MA 01887
  - FEI: 3003395329
- TJOAPACK, LLC
  - 341 JD YARNELL INDUSTRIAL PARKWAY, CLINTON, TN 37716
  - FEI: 3002763532
- TULEX PHARMACEUTICALS, INC.
  - 5 CEDARBROOK DRIVE, CRANBURY, NJ 08512
  - FEI: 3011875665
- GCP LABORATORIES
  - 3600 25TH AVENUE, GULFPORT, MS 39501
  - FEI: 965480861
- EISAI, INC.
  - 11675 CROSSROADS CIRCLE, BALTIMORE, MD 21220
  - FEI: 1000158705
- PATHEON PHARMACEUTICALS, INC.
  - 2110 E GALBRAITH ROAD, CINCINNATI, OH 45237
  - FEI: 1510437
- SAFECOR HEALTH, LLC
  - 4060 BUSINESS PARK DRIVE, COLUMBUS, OH 43204
  - FEI: 3008841077
- PATHEON, INC.
  - 111 CONSUMERS DRIVE, WHITBY, ONTARIO L5N 7K9, CANADA (CAN)
  - FEI: 3003516812
- GALENICA S.A.
  - 3RD KM OLD NATIONAL ROAD CHALKIDA ATHENS, CHALCIS, 34100, GREECE (GRC)
  - FEI: 3012189222
- ANDERSONBRECON, INC. DBA PCI PHARMA SERVICES
  - 4545 ASSEMBLY DRIVE, ROCKFORD, IL 61109
  - FEI: 1421377

THIRD-PARTY LOGISTICS PROVIDER

- CARDINAL HEALTH DBA SPECIALTY PHARMACEUTICAL SERVICES
    - 501 MASON ROAD, SUITE 200, LA VERGNE, TN 37086
    - 15 INGRAM BOULEVARD, LA VERGNE, TN 37086

AZURITY PHARMACEUTICALS, INC.

8 CABOT ROAD, SUITE 2000
WOBURN, MA 01801

TOP FOUR SUPPLIERS

AMERISOURCEBERGEN BETHLEHEM	5100 JAINDL BLVD	BETHLEHEM	PA	18017
AMERISOURCEBERGEN BUFORD	3930 MASON MILL RD NE	BUFORD	GA	30518
AMERISOURCEBERGEN CORONA	1851 CALIFORNIA AVE	CORONA	CA	92881
AMERISOURCEBERGEN DENVER	501 W 44TH AVE	DENVER	CO	80216
AMERISOURCEBERGEN DES MOINES	2141 S 211TH ST STE A	DES MOINES	WA	98198
AMERISOURCEBERGEN RICHMOND	9900 JEB STUART PKWY	GLEN ALLEN	VA	23059
JM BLANCO AMERISOURCEBERGEN	CALLE DIANA LOTE 21 AMELIA	GUAYNABO	PR	00968
AMERISOURCEBERGEN HONOLULU	238 SAND ISLAND ACCESS RD M1	HONOLULU	HI	96819
AMERISOURCEBERGEN KANSAS CITY	11200 N CONGRESS AVE	KANSAS CITY	MO	64153
AMERISOURCEBERGEN LOCKBOURNE	6305 LASALLE DR	LOCKBOURNE	OH	43137
AMERISOURCEBERGEN LOUISVILLE	6001 GLOBAL DIST WAY STE 102	LOUISVILLE	KY	40228
AMERISOURCEBERGEN MANSFIELD	101 NORFOLK ST	MANSFIELD	MA	02048
AMERISOURCEBERGEN MORRISVILLE	120 TRANS AIR DR	MORRISVILLE	NC	27560
AMERISOURCEBERGEN AMITYVILLE	5500 NEW HORIZONS BLVD	N AMITYVILLE	NY	11701
AMERISOURCEBERGEN NEWBURGH	108 RTE 17K STE 1	NEWBURGH	NY	12550
AMERISOURCEBERGEN OLIVE BRANCH	12577 STATE LINE RD	OLIVE BRANCH	MS	38654
AMERISOURCEBERGEN ORLANDO	10910 LEE VISTA BLVD STE 401	ORLANDO	FL	32829
AMERISOURCEBERGEN PHOENIX	7775 W BUCKEYE RD STE 150	PHOENIX	AZ	85043
AMERISOURCEBERGEN ROANOKE	501 PATRIOT PKWY	ROANOKE	TX	76262
AMERISOURCEBERGEN ROMEOVILLE	1001 W TAYLOR RD	ROMEOVILLE	IL	60446
AMERISOURCEBERGEN SACRAMENTO	1325 W STRIKER AVE	SACRAMENTO	CA	95834
AMERISOURCEBERGEN SALT LAKE CIT\	1765 FREMONT DR	SALT LAKE CITY	UT	84104
AMERISOURCEBERGEN SHAKOPEE	500 INNOVATION DR	SHAKOPEE	MN	55379
AMERISOURCEBERGEN SUGARLAND	12727 W AIRPORT BLVD	SUGARLAND	TX	77478
AMERISOURCEBERGEN WHITESTOWN	4860 INDIANAPOLIS RD	WHITESTOWN	IN	46075
AMERISOURCEBERGEN WILLIAMSTON	1 INDUSTRIAL PARK DR	WILLIAMSTON	MI	48895
CARDINAL HEALTH AUBURN	801C STREET NW	AUBURN	WA	98001
CARDINAL HEALTH AURORA	2353 PROSPECT DRIVE	AURORA	IL	60502
CARDINAL HEALTH DENVER	4875 FLORENCE STREET	DENVER	CO	80238
CARDINAL HEALTH ELK GROVE	3238 DWIGHT ROAD	ELK GROVE	CA	95758
CARDINAL HEALTH GREENSBORO	4 CARDINAL HEALTH COURT	GREENSBORO	NC	27407
CARDINAL HEALTH GROVEPORT	5995 COMMERCE CENTER DR	GROVEPORT	OH	43125
CARDINAL HEALTH HUDSON	2901 ENLOE STREET	HUDSON	WI	54016
CARDINAL HEALTH KANSAS CITY	7601 NE GARDNER AVENUE	KANSAS CITY	MO	64120
CARDINAL HEALTH KNOXVILLE	2512 WESTCOTT BOULEVARD	KNOXVILLE	TN	37931
CARDINAL HEALTH LAKELAND	2045 INTERSTATE DRIVE	LAKELAND	FL	33805
CARDINAL HEALTH JACKSON	1240 GLUCKSTADT ROAD	MADISON	MS	39110
CARDINAL HEALTH 110	5960 E SHELBY DR STE 100	MEMPHIS	TN	38141
CARDINAL HEALTH PEABODY	11 CENTENNIAL DRIVE	PEABODY	MA	01960
CARDINAL HEALTH ROANOKE	851 HENRIETTA CREEK ROAD	ROANOKE	TX	76262
CARDINAL HEALTH SALT LAKE CITY	955 WEST 3100 SOUTH	SALT LAKE CITY	UT	84119
CARDINAL HEALTH ST CHARLES	2840 ELM POINT IND PARKWAY	ST. CHARLES	MO	63301
CARDINAL HEALTH STAFFORD	13651 DUBLIN CT	STAFFORD	TX	77477
CARDINAL HEALTH SWEDESBORO	1120 COMMERCE BLVD	SWEDESBORO	NJ	08085
CARDINAL HEALTH SYRACUSE	6012 E. MOLLOY ROAD	SYRACUSE	NY	13211
CARDINAL HEALTH TOLLESON	600 NORTH 83RD AVENUE	TOLLESON	AZ	85353
CARDINAL HEALTH VALENCIA	27680 AVENUE MENTRY	VALENCIA	CA	91355
CARDINAL HEALTH WHEELING	71 MIL ACRES DRIVE	WHEELING	WV	26003
CARDINAL HEALTH WHITESTONE	152-35 10TH AVENUE	WHITESTONE	NY	11357
MCKESSON CORPORATION ANCHORAC	5491 ELECTRON DRIVE SUITE A	ANCHORAGE	AK	99518
MCKESSON CORPORATION CHICAGOL/	1995 MCKESSON ST	AURORA	IL	60502
MCKESSON DRUG CORPORATION DEN	14500 E 39TH AVE	AURORA	CO	80011
MCKESSON CORPORATION CLEAR LAK	2101 12TH AVE S	CLEAR LAKE	IA	50428
MCKESSON CORPORATION CONROE	3301 POLLOK DRIVE	CONROE	TX	77303
MCKESSON CORPORATION ATLANTA	2975 EVERGREEN DR	DULUTH	GA	30096

MCKESSON MICHIGAN DC	1961 HOLLOWAY DRIVE	HOLT	MI	48842
MCKESSON HONOLULU	80 SAND ISLAND ACCESS RD	HONOLULU	HI	96819
MCKESSON CORP JEFFERSONVILLE	8200 BLUEGRASS BLVD	JEFFERSONVILLE	OH	43128
MCKESSON CORPORATION LAKELAND	1515 KENDRICK LANE	LAKELAND	FL	33805
MCKESSON CORPORATION BIRMINGHA	6775 JEFFERSON METROPOLITAN	MCCALLA	AL	35111
MCKESSON CORPORATION MEMPHIS	4836 SOUTHRIDGE BLVD	MEMPHIS	TN	38141
MCKESSON CORPORATION METHUEN	9 AEGEAN DR	METHUEN	MA	01844
MCKESSON MONTGOMERY NY METRO	10 HUDSON CROSSING DR	MONTGOMERY	NY	12549
MCKESSON CORPORATION ST LOUIS	1 COMMERCE DR	O'FALLON	MO	63366
MCKESSON CORPORATION OKLAHOM/	4012 S PURDUE AVE	OKLAHOMA CITY	OK	73179
MCKESSON OLIVE BRANCH	8313 POLK LANE	OLIVE BRANCH	MS	38654
MCKESSON CORP PUYALLUP	208 TODD RD NE	PUYALLUP	WA	98372
MCKESSON CORPORATION DC 8155	1 JOHN HENRY DRIVE	ROBBINSVILLE	NJ	08691
MCKESSON CORPORATION RUTHER GL	10504 MCKESSON DRIVE	RUTHER GLEN	VA	22546
MCKESSON CORPORATION SALT LAKE	1900 SOUTH 4490 WEST	SALT LAKE CITY	UT	84104
MCKESSON CORPORATION SOCAL	9501 NORWALK BLVD	SANTA FE SPRINC	CA	90670
MCKESSON CORPORATION TOLLESON	495 S 107TH	TOLLESON	AZ	85353
MCKESSON CORPORATION WEST SAC	3775 SEAPORT BLVD	WEST SACRAMEN	CA	95691
MCKESSON CORPORATION BUFFALO	2700 NORTH AMERICA DRIVE	WEST SENECA	NY	14224
MCKESSON CORPORATION WILSONVIL	9700 SW COMMERCE CIRCLE	WILSONVILLE	OR	97070
MORRIS DICKSON SHREVEPORT	10301 HWY 1 S	SHREVEPORT	LA	71115

Ship-To Name	Ship-To Address	City	State	Zip
AMERISOURCEBERGEN E	5100 JAINDL BLVD	BETHLEHEM	PA	18017
AMERISOURCEBERGEN E	3930 MASON MILL RD NE	BUFORD	GA	30518
AMERISOURCEBERGEN C	1851 CALIFORNIA AVE	CORONA	CA	92881
AMERISOURCEBERGEN D	501 W 44TH AVE	DENVER	CO	80216
AMERISOURCEBERGEN D	2141 S 211TH ST STE A	DES MOINES	WA	98198
AMERISOURCEBERGEN F	9900 JEB STUART PKWY	GLEN ALLEN	VA	23059
JM BLANCO AMERISOUR	CALLE DIANA LOTE 21 AMELIA	GUAYNABO	PR	00968
AMERISOURCEBERGEN H	238 SAND ISLAND ACCESS RD M1	HONOLULU	HI	96819
AMERISOURCEBERGEN K	11200 N CONGRESS AVE	KANSAS CITY	MO	64153
AMERISOURCEBERGEN L	6305 LASALLE DR	LOCKBOURNE	OH	43137
AMERISOURCEBERGEN L	6001 GLOBAL DIST WAY STE 102	LOUISVILLE	KY	40228
AMERISOURCEBERGEN M	101 NORFOLK ST	MANSFIELD	MA	02048
AMERISOURCEBERGEN M	120 TRANS AIR DR	MORRISVILLE	NC	27560
AMERISOURCEBERGEN A	5500 NEW HORIZONS BLVD	N AMITYVILLE	NY	11701
AMERISOURCEBERGEN N	108 RTE 17K STE 1	NEWBURGH	NY	12550
AMERISOURCEBERGEN C	12577 STATE LINE RD	OLIVE BRANCH	MS	38654
AMERISOURCEBERGEN C	10910 LEE VISTA BLVD STE 401	ORLANDO	FL	32829
AMERISOURCEBERGEN P	7775 W BUCKEYE RD STE 150	PHOENIX	AZ	85043
AMERISOURCEBERGEN R	501 PATRIOT PKWY	ROANOKE	TX	76262
AMERISOURCEBERGEN R	1001 W TAYLOR RD	ROMEOVILLE	IL	60446
AMERISOURCEBERGEN S	1325 W STRIKER AVE	SACRAMENTO	CA	95834
AMERISOURCEBERGEN S	1765 FREMONT DR	SALT LAKE CITY	UT	84104
AMERISOURCEBERGEN S	500 INNOVATION DR	SHAKOPEE	MN	55379
AMERISOURCEBERGEN S	12727 W AIRPORT BLVD	SUGARLAND	TX	77478
AMERISOURCEBERGEN V	4860 INDIANAPOLIS RD	WHITESTOWN	IN	46075
AMERISOURCEBERGEN V	1 INDUSTRIAL PARK DR	WILLIAMSTON	MI	48895
CARDINAL HEALTH AUBL	801C STREET NW	AUBURN	WA	98001
CARDINAL HEALTH AURC	2353 PROSPECT DRIVE	AURORA	IL	60502
CARDINAL HEALTH DENV	4875 FLORENCE STREET	DENVER	CO	80238
CARDINAL HEALTH ELK G	3238 DWIGHT ROAD	ELK GROVE	CA	95758
CARDINAL HEALTH GREE	4 CARDINAL HEALTH COURT	GREENSBORO	NC	27407
CARDINAL HEALTH GROV	5995 COMMERCE CENTER DR	GROVEPORT	OH	43125
CARDINAL HEALTH HUDS	2901 ENLOE STREET	HUDSON	WI	54016
CARDINAL HEALTH KANS	7601 NE GARDNER AVENUE	KANSAS CITY	MO	64120
CARDINAL HEALTH KNOX	2512 WESTCOTT BOULEVARD	KNOXVILLE	TN	37931
CARDINAL HEALTH LAKE	2045 INTERSTATE DRIVE	LAKELAND	FL	33805
CARDINAL HEALTH JACK	1240 GLUCKSTADT ROAD	MADISON	MS	39110
CARDINAL HEALTH 110	5960 E SHELBY DR STE 100	MEMPHIS	TN	38141
CARDINAL HEALTH PEAB	11 CENTENNIAL DRIVE	PEABODY	MA	01960
CARDINAL HEALTH ROAN	851 HENRIETTA CREEK ROAD	ROANOKE	TX	76262
CARDINAL HEALTH SALT	955 WEST 3100 SOUTH	SALT LAKE CITY	UT	84119
CARDINAL HEALTH ST CH	2840 ELM POINT IND PARKWAY	ST. CHARLES	MO	63301
CARDINAL HEALTH STAF	13651 DUBLIN CT	STAFFORD	TX	77477
CARDINAL HEALTH SWEI	1120 COMMERCE BLVD	SWEDESBORO	NJ	08085
CARDINAL HEALTH SYRA	6012 E. MOLLOY ROAD	SYRACUSE	NY	13211
CARDINAL HEALTH TOLL	600 NORTH 83RD AVENUE	TOLLESON	AZ	85353
CARDINAL HEALTH VALE	27680 AVENUE MENTRY	VALENCIA	CA	91355
CARDINAL HEALTH WHEE	71 MIL ACRES DRIVE	WHEELING	WV	26003
CARDINAL HEALTH WHIT	152-35 10TH AVENUE	WHITESTONE	NY	11357
MCKESSON CORPORATIO	5491 ELECTRON DRIVE SUITE A	ANCHORAGE	AK	99518
MCKESSON CORPORATIO	1995 MCKESSON ST	AURORA	IL	60502
MCKESSON DRUG CORP	14500 E 39TH AVE	AURORA	CO	80011
MCKESSON CORPORATIO	2101 12TH AVE S	CLEAR LAKE	IA	50428
MCKESSON CORPORATIO	3301 POLLOK DRIVE	CONROE	TX	77303

MCKESSON CORPORATI(	2975 EVERGREEN DR	DULUTH	GA	30096
MCKESSON MICHIGAN D(	1961 HOLLOWAY DRIVE	HOLT	MI	48842
MCKESSON HONOLULU	80 SAND ISLAND ACCESS RD	HONOLULU	HI	96819
MCKESSON CORP JEFFE(	8200 BLUEGRASS BLVD	JEFFERSONVILLE	OH	43128
MCKESSON CORPORATI(	1515 KENDRICK LANE	LAKELAND	FL	33805
MCKESSON CORPORATI(	6775 JEFFERSON METROPOLITAN	MCCALLA	AL	35111
MCKESSON CORPORATI(	4836 SOUTHRIDGE BLVD	MEMPHIS	TN	38141
MCKESSON CORPORATI(	9 AEGEAN DR	METHUEN	MA	01844
MCKESSON MONTGOME(	10 HUDSON CROSSING DR	MONTGOMERY	NY	12549
MCKESSON CORPORATI(	1 COMMERCE DR	O'FALLON	MO	63366
MCKESSON CORPORATI(	4012 S PURDUE AVE	OKLAHOMA CITY	OK	73179
MCKESSON OLIVE BRAN(	8313 POLK LANE	OLIVE BRANCH	MS	38654
MCKESSON CORP PUYAL	208 TODD RD NE	PUYALLUP	WA	98372
MCKESSON CORPORATI(	1 JOHN HENRY DRIVE	ROBBINSVILLE	NJ	08691
MCKESSON CORPORATI(	10504 MCKESSON DRIVE	RUTHER GLEN	VA	22546
MCKESSON CORPORATI(	1900 SOUTH 4490 WEST	SALT LAKE CITY	UT	84104
MCKESSON CORPORATI(	9501 NORWALK BLVD	SANTA FE SPRING	CA	90670
MCKESSON CORPORATI(	495 S 107TH	TOLLESON	AZ	85353
MCKESSON CORPORATI(	3775 SEAPORT BLVD	WEST SACRAMEN	CA	95691
MCKESSON CORPORATI(	2700 NORTH AMERICA DRIVE	WEST SENECA	NY	14224
MCKESSON CORPORATI(	9700 SW COMMERCE CIRCLE	WILSONVILLE	OR	97070
MORRIS DICKSON SHREV	10301 HWY 1 S	SHREVEPORT	LA	71115

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: CITAGENIX REGEN, LLC

Physical Address: 39555 Orchard Hill Place, Suite 600

City: Novi State: MI Zip: 48375

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: [redacted] Website: https://www.citagenix.com/

Name of Designated Representative (DR): Melody Stimbert

Licensing Company Email: ra-regen@citagenix.com DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: HCT/Ps	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Full-service

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: COLLAGEN MATRIX, INC.
Address: 15 Thornton Rd City: Oakland State: NJ Zip: 07436

Name: PURGO BIOLOGICS INC.
Address: #812, 27, Dunchon-Daero 457 Beon-Gil, Jungwon-Gu City: Seongnam-Si State: Gyeonggi Zip: 13219

Name: RESORBA Medical GmbH
Address: AM FLACHMOOR 16 City: NUREMBERG State: Bavaria Zip: D-90475

Name: HANS BIOMED CORP.
Address: 64, YUSEONG-DAERO 1628 BEON-GIL City: Yuseong-Gu State: Daejeon Zip: 34054

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Michigan
Parent Company (if any): HANSAmed Limited
Corporation/Organization Name: CITAGENIX REGEN, LLC
Mailing Address: 39555 Orchard Hill Place, Suite 600
City: Novi State: MI Zip: 48375
Telephone: [redacted] Email: [redacted]
Contact Person Name: [redacted]

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Citagenix Regen, LLC

Facility Name

Maik Rehfeldt

Print Name of Authorized Person Submitting Application

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

June 3rd, 2024

Date

Board Use Only	Date Received: 6/11/24	Amount: $2000-CC

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
CITAGENIX REGEN, LLC
39555 Orchard Hill Place, Suite 600
Novi, MI 48375
Registration Number: 3030462407
FEI Number*: 3030462407
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types
Please Review Listings For Further Information
Date Of Registration Status: 2024

Owner/Operator:
CITAGENIX REGEN, LLC[6]
39555 Orchard Hill Place, Suite 600
Novi, MI US 48375
Owner/Operator Number: 10090282[7]

Official Correspondent:
Heather Zhang
39555 Orchard Hill Place, Suite 600
Novi, MI 48375
[redacted]

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified MH 6/12/24

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10090282&OwnerOperatc
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Page Last Updated: 05/06/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of Health & Human Services

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10090282&OwnerOperatc

7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10090282&OwnerOperatc

U.S. FOOD & DRUG ADMINISTRATION

FDA Home Page | Contact eHCTERS Technical Support

HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION - Public Query
Establishment Details

Establishment Name and Location

Current Status:	Registered
Last Annual Registration Year:	2024
FDA Establishment Identifier (FEI):	3030462407
Establishment Name:	CITAGENIX REGEN, LLC
Address:	39555 Orchard Hill Place, Suite 600
City:	Novi
State:	Michigan
Zip:	48375
Country:	UNITED STATES
Phone:	248-240-0386

Establishment Functions

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane						☑		☑
Blood Vessel								
Bone						☑		☑
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis								
HPC Cord Blood								
Ligament								
Nerve Tissue								
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium								
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera								
Semen								
Skin						☑		☑
Tendon								

Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue								

Establishment HCT/P Listing

Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Proprietary Names
Amniotic Membrane	X	Neomem XAC
Blood Vessel		
Bone	X	Raptos, PentOS OI, Mit-Os
Cardiac Tissue - non-valved		
Cartilage		
Cornea		
Dura Mater		
Embryo		
Fascia		
Heart Valve		
HPC Apheresis		
HPC Cord Blood		
Ligament		
Nerve Tissue		
Oocyte		
Ovarian Tissue		
Pancreatic Islet Cells - autologous		
Parathyroid		
Pericardium		
Peripheral Blood Mononuclear Cells		
Peritoneal Membrane		
Sclera		
Semen		
Skin	X	NeoDerm
Tendon		
Testicular Tissue		
Tooth Pulp		
Umbilical Cord Tissue		

HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis					
HPC Cord Blood					
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

Print Date: 05/08/2024

Print This Page | Back To Query Criteria Screen | Back To Query Results Screen | Exit

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Updated 04/11/2024

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FDA / Center for Biologics Evaluation and Research

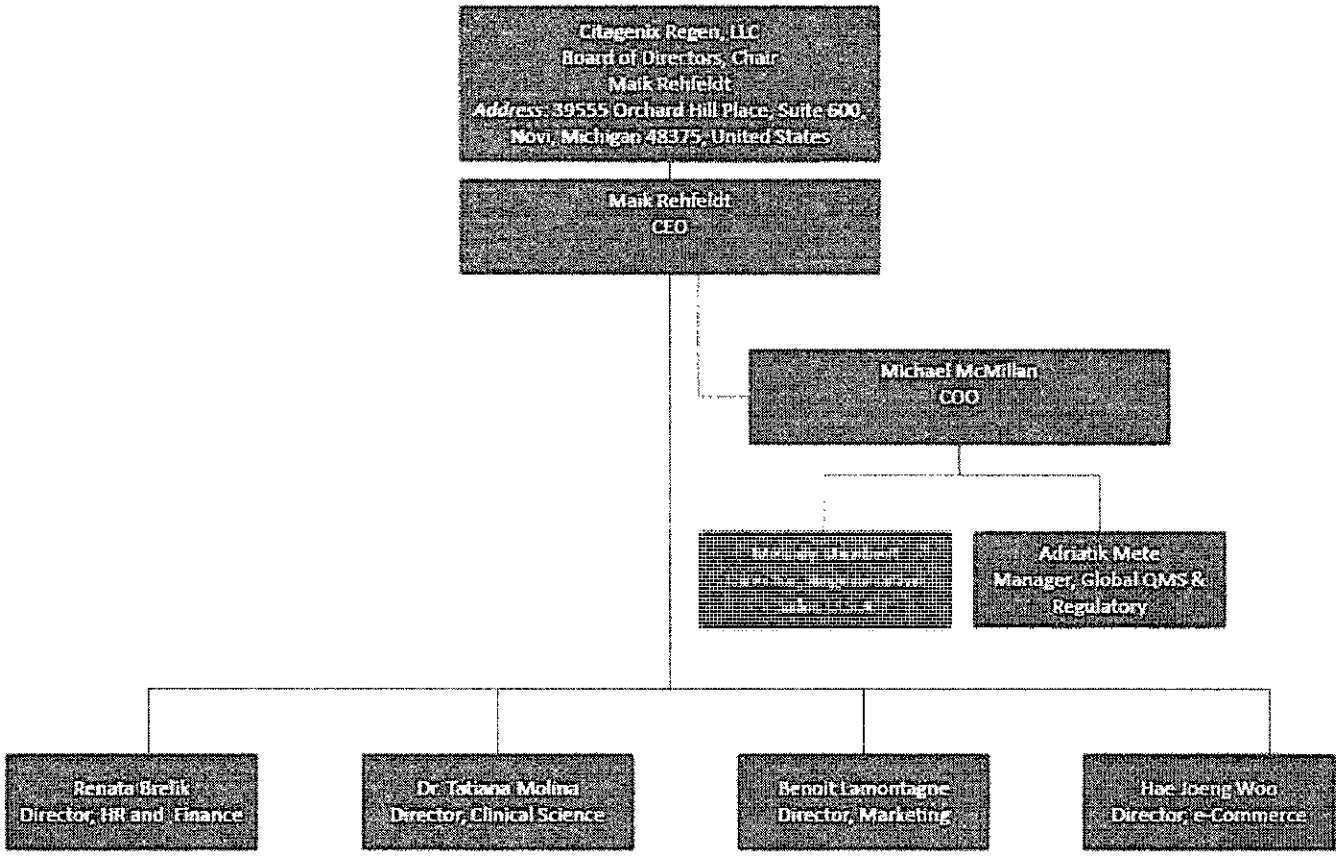
HANSAmed LIMITED | CITAGENIX

Corporate Structure and Ownership

Citagenix Regen, LLC

EIN: 98-1739050 *(taxpayer Id number)*
Business address: *39555 Orchard Hill Place, Suite 600, Novi, Michigan 48375, United States*
Business information: Citagenix Regen, LLC is a subsidiary of HANSAmed Limited

STRUCTURE



MANAGEMENT
Management details in table below

Name of Director /Manager	Title, role	Business address	Date of Birth	Phone #
Melody Stimbert	Director, Regenerative Sales USA	39555 Orchard Hill Place, Suite 600, Novi, Michigan 48375, United States	[redacted]	[redacted]
Adriatik Mete	Manager, Global QMS & Regulatory	2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada	[redacted]	[redacted]

OWNERSHIP

Ownership type: *Private*
Citagenix Regen, LLC is a Michigan Limited Liability Company wholly owned by HANSAmed Limited, a Canadian company registered in the province of Ontario.

Ownership details in table below.

Name of Entity	Title, role	Business address	Date of Birth	% of Company Owned	Phone #	Social Security /Insurance Number
HANSAmed Limited	Parent company	2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada	N/A	100	[redacted]	N/A

Maik Rehfeldt
CEO, HANSAmed Limited

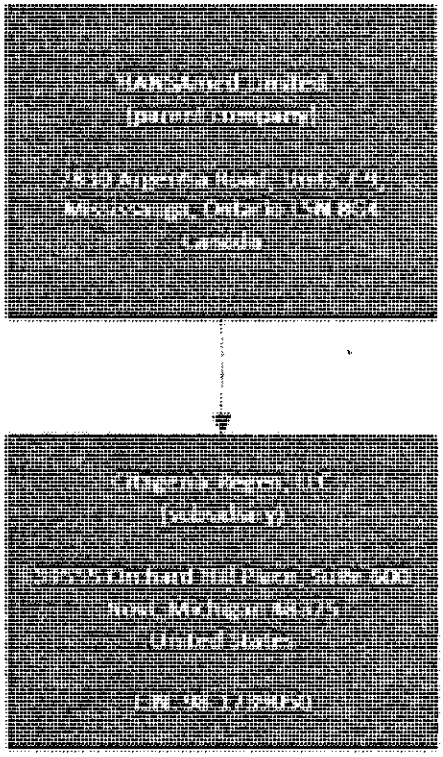
HANSAmed LIMITED | CITAGENIX
A SUBSIDIARY OF HANSAMED LIMITED

Corporate Structure and Ownership

HANSAmed Limited
Parent company, a Canadian company.

Business address: *2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4 Canada*
Business information: HANSAmed Limited owns the following companies: Citagenix, Inc, Laval, Quebec; Citagenix Regen, LLC, Novi, Michigan, United States

STRUCTURE



HANSAmed LIMITED | CITAGENX
A SUBSIDIARY OF HANSAMED LIMITED

OWNERSHIP

Ownership type: *Private*
HANSAmed Limited is a Canadian company registered in province of Ontario.

Ownership details for HANSAmed Limited in table below.

Name of Board Member /Corporate Officer	Title, role	Business address	Date of Birth	% of Company Owned	Phone #	Social Security /Insurance Number
Maik Rehfeldt (Board Member)	CEO	2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada	[redacted]	[redacted]	[redacted]	[redacted]
Henry Schein Canada, Inc.	Corporate Officer	345 Townline Road, Niagara-on-the-Lake, Ontario L0S 1J0, Canada	N/A	[redacted]	[redacted]	Public Company; trading symbol: HSIC

Maik Rehfeldt
CEO, HANSAmed Limited

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

CITAGENIX REGEN, LLC

was validly authorized on April 10 , 2023, as a Michigan
DOMESTIC LIMITED LIABILITY COMPANY
and said limited liability company is validly in existence under the laws of this state and has satisfied its annual filing obligations.

This certificate is issued pursuant to the provisions of 1993 PA 23 to attest to the fact that the company is in good standing in Michigan as of this date.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand,
in the City of Lansing, this 8th day of May , 2024.

Linda Clegg

Linda Clegg, Director
Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24050162208

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

5306007819APP24

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

CITAGENIX REGEN, LLC
39555 ORCHARD HILL PLACE, SUITE
600
NOVI, MI 48375

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

CITAGENIX REGEN, LLC
39555 ORCHARD HILL PLACE, SUITE 600
NOVI, MI 48375

LICENSE NO.
5306007819

EXPIRATION DATE
05/03/2026

24124130507

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

CERTIFICATE OF INSURANCE

DATE
May 17, 2024

BROKER

Jones DesLauriers Insurance Management, Inc.
2375 Skymark Avenue,
Mississauga, ON , L4W 4Y6
[redacted]

This certificate is issued as a matter of information only and confers no rights upon the certificate holder. This certificate does not amend, extend or alter the coverage afforded by the policies below.

INSURED

Hansamed Limited & Citagenix Regen, LLC
2830 Argentia Rd., Units 5-9
Mississauga, ON L5N 8G4

COMPANIES AFFORDING COVERAGE

COMPANY A	Certain Lloyd's Underwriters c/o Ed Broking LLP
COMPANY B	
COMPANY C	
COMPANY D	

COVERAGES

This is to certify that the policies of insurance listed below have been issued to the insured named above for the policy period indicated, notwithstanding any requirement, term or condition of any contract or other document with respect to which this certificate may be issued or may pertain. The insurance afforded by the policies described herein is subject to all the terms, exclusions and conditions of such policies. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

CO LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE (YYYY/MM/DD)	POLICY EXPIRATION DATE (YYYY/MM/DD)	LIMITS	
	COMMERCIAL GENERAL LIABILITY					
	X CLAIMS MADE-PRODUCTS	[redacted]	2023-12-31	2024-12-31	BODILY INJURY & PROPERTY DAMAGE INCLUSIVE LIMITS	$5,000,000.
	X OCCURRENCE-ALL EXCEPT PRODUCTS				GENERAL AGGREGATE	$5,000,000.
	X PRODUCTS AND/OR COMPLETED OPERATIONS				PRODUCTS / COMPLETED OPERATIONS AGGREGATE	$5,000,000.
	X TENANTS LEGAL LIABILITY				TENANTS LEGAL LIABILITY	$1,000,000.
	X NON-OWNED AUTOMOBILE				NON-OWNED AUTOMOBILE	$1,000,000.

DESCRIPTION OF OPERATIONS/LOCATIONS/SPECIAL CONDITIONS/OTHER: **Note: Limits are Stated in Canadian Dollars.**

Description of Operations: Operations normal to the business of the Insured.
Citagenix Regen, LLC, 39555 Orchard Hill Place, Suite 600, Novi, Michigan 48375

CERTIFICATE HOLDER

Attn: Fax:

CANCELLATION

Should any of the above described policies be cancelled before the expiration date thereof, the issuing company will endeavour to mail **(0) days** written notice to the certificate holder named to the left, but failure to mail such notice shall impose no obligation or liability of any kind upon the company, its agents or representatives.

AUTHORIZED REPRESENTATIVE: Kathy Gallagher, CAIB, CIP
Jones DesLauriers Insurance Management, Inc.

(8) $25,000 Surety bond

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 015223890

Application/License No. _____

CITAGENIX REGEN, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 39555 Orchard Hill Place, Suite 600 Novi, MI 48375 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 16, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of May, 2024.

APPLICANT/PRINCIPAL
CITAGENIX REGEN, LLC

Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sandra Diaz, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness
Laura von Heynitz

Witness

SIGNED and SEALED in the presence of:

Witness Grace Laterza

Witness Anne Potter

Countersigned by:

Nevada Resident Agent Aklima Noorhassan
Non-Resident Agent NV License No. 3163993

Posted February 20, 2020

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8210937- 015009**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Debra A. Deming, Sandra Diaz, Vilma Gonzalez, Peter Healy, Pablo Garcia Horcajo, Jennifer L. Jakaitis, Francesca Kazmierczak, Aklima Noorhassan, Anne Potter, Frances Rodriguez, Valorie Spates, Susan A. Welsh, Beverly A. Woolford

all of the city of New York state of NY each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 6th day of November, 2023.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 6th day of November, 2023 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 16th day of May, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2023

Assets

Cash and Bank Deposits	$1,850,245,073.00
*Bonds – U.S Government	$3,859,565,383.00
*Other Bonds	$21,048,805,773.00
*Stocks	$19,937,271,802.00
Real Estate	$122,228,711.00
Agents' Balances or Uncollected Premiums	$8,208,660,427.00
Accrued Interest and Rents	$186,906,667.00
Other Admitted Assets	$15,677,869,683.63
Total Admitted Assets	**$70,891,553,519.63**

Liabilities

Unearned Premiums	$10,298,963,305.00
Reserve for Claims and Claims Expense	$28,848,537,243.00
Funds Held Under Reinsurance Treaties	$360,714,151.00
Reserve for Dividends to Policyholders	$1,310,198.00
Additional Statutory Reserve	$296,126,000.00
Reserve for Commissions, Taxes and Other Liabilities	$7,622,413,466.63
Total	**$47,428,064,363.63**
Special Surplus Funds	$209,508,757.00
Capital Stock	$10,000,075.00
Paid in Surplus	$13,834,867,488.00
Unassigned Surplus	$9,409,112,836.00
Surplus to Policyholders	$23,463,489,156.00
Total Liabilities and Surplus	**$70,891,553,519.63**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2023, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2024.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG CITAGENIX REGEN, LLC MDEG License # (if applicable) N/A

Physical Address 39555 Orchard Hill Place, Suite 600

City Novi State MI Zip 48375

Mailing Address (if different from physical address) N/A

City _____ State _____ Zip _____

Telephone [redacted] Website https://www.citagenix.com/

Licensing Company Email [redacted]

Section 2: Personal Information

First Melody Middle Lynn Last Stimbert

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 39555 Orchard Hill Place, Suite 600

City Novi State MI Zip 48375

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LOWELL HIGH SCHOOL		09/72-06/76	
Address	**City**	**State**	**Zip**
16200 E AMBER VALLEY DRIVE	WHITTIER	CA	90604
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/20-Present	[redacted]	Highland	MI	48357
12/93-11/20	[redacted]	Highland	MI	48356
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Citagenix			10/16-Present	
Business Address	**City**		**State**	**Zip**
39555 Orchard Hill Place, Suite 600	Novi		MI	48375
Phone	**Title**		**Number of Employed Hours**	
1-248-240-0386	Director Regenerative Sales, U.S.A.		15000	
Description of Duties				
Business developer, sales and marketing specialist .				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Melody Stimbert, **certify that as the MDEG Administrator for**

CITAGENIX REGEN, LLC,

that I (initial that you have read and meet the following requirements):

1. MS Have a high school diploma or its equivalent;
2. MS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Melody Stimbert
Print Name (First, Last)

[redacted]
Original Signature (electronic, copies or stamps not accepted)

May 8, 2024
Date

Board Use Only	Date Received: 6/11/24

Melody Stimbert

[redacted]

Business developer, sales and marketing specialist combining creativity with 30 years of distinguished sales experience. Expert skills in determining market trends, competitive products, contributor to corporate bottom line and strategic planning. Track record of management success, building successful teams to perform and succeed.

Success-driven … Dynamic sales leadership … Exceptional relationship building

Professional Training:

University of Chicago; Graduate School of Business –
"Fundamentals of Effective Sales Management"
SPIN Selling
Dale Carnegie – "Customer Service and Supervisor/Management Role"

Citagenix **Oct 2016 – Present**
Laval, Canada

Director Regenerative Sales, U.S.

- Establish distribution channel through drop ship and stocking distributors throughout the United States
- Develop and acquire Independent Representatives
- Train and develop distributor representatives
- Establish relationships with Distributor Management Teams to enable growth and increase marketing projections

MS Biologics, LLC **July 2010 – Oct 2016**
Highland, Michigan

Owner

Established FDA registered Distribution Company of tissue regeneration products within the Dental market of North America. Quickly became a leader in the bone grafting market

- Within first 3 years' sales growth over $500k
- Developed Independent Representative Sales Organization of 40
- Created Business strategy and marketing plans for continued growth quarter over quarter; year over year.
- Built extensive inventory; managed profit and loss

Keystone Dental **Sept 2006 – July 2010**
Burlington, Massachusetts

Early stage medical device company which manufactured and distributed a complete line of dental implants, bone regenerative products along with newer technology digital dentistry software.

Great Lakes Regional Manager

- 2009 Regional Manager of the Year; 1 of 6; 110%
  - Managed 17 State Geography; 8 Sales Executives; $8mm Sales Revenue: 20% of worldwide company revenue
- 2008 Regional Manager of the Year; 1 of 7; 109%
  - Managed 10 State Geography; 7 Sales Executives; $5.5mm Sales Revenue
- 2007 District Manager of the Year; 1 of 9; 112%
  - Consistently exceeded monthly sales goals; 15 months in a row

Straumann, USA **June 2004 – Sept 2006**
Andover, Massachusetts

World wide leader of complete line of dental implant products.

Sales Manager – Michigan Territory

- Responsible for growing sales territory from less than $300,000 annual sales to over $1.5mm in 18months.
- Exceeded sales quota and growth objectives for 2004 & 2005.
- Great Lakes Region Representative of the Year; 2004 & 2005.
- 2004, ranked #5 of 80 in the U.S. Sales organization
- 2005, ranked #7 of 120 in the U.S. Sales
- President's Club Award Winner – 2004, 2005
- Field Sales Trainer; Sales Advisory Board Member

Nobel Biocare, USA
Yorba Linda, CA

Largest volume manufacturer of complete line of dental implants and prosthetic attachments.

Territory Manager – Detroit **April 1993 – April 2004**

- Responsible for growing and achieving double digit growth in territory for ten consecutive years.
- Consistently achieving sales goals and exceeding growth expectations.
- Awarded President's Club 1996, 1998, 2000, 2001 & 2003
- Great Lakes Region Representative of the Year; 1996 and 1998
- Developed successful marketing and sales strategies for obtaining new customers-through direct mail, cold calling, and telemarketing.
- Organized and presented technical continuing education courses to customers and their staff.
- Field Sales Trainer

References available upon request

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler CITAGENIX REGEN, LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 39555 Orchard Hill Place, Suite 600

City Novi State MI Zip 48375

Mailing Address (if different from physical address) N/A

City N/A State N/A Zip N/A

Telephone [redacted] Website https://www.citagenix.com/

Licensing Company Email [redacted]

Section 2: Personal Information

First Melody Middle Lynn Last Stimbert

Alias(es, nicknames, name changes, etc.) Melody Lynn Zaugg

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 39555 Orchard Hill Place, Suite 600

City Novi State MI Zip 48375

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LOWELL HIGH SCHOOL		09/72-06/76	
Address	**City**	**State**	**Zip**
16200 E AMBER VALLEY DRIVE	WHITTIER	CA	90604
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/20-Present	[redacted]	Highland	MI	48357
12/93-11/20	[redacted]	Highland	MI	48356

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Citagenix			10/16-Present	
Business Address		**City**	**State**	**Zip**
39555 Orchard Hill Place, Suite 600		Novi	MI	48375
Phone	**Title**		**Number of Employed Hours**	
1-905-813-8090	Director Regenerative Sales, U.S.A.		15000	
Description of Duties				
Business developer, sales and marketing specialist.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Melody Stimbert, **certify that as the designated representative for**

CITAGENIX REGEN, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MS I am at least 21 years of age;
3. MS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Melody Stimbert

[redacted]

Original Signature (electronic, copies or stamps not accepted)

April 08, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Melody Stimbert

[redacted]

Original Signature (electronic, copies or stamps not accepted)

April 8, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Oakland

I, Melody Stimbert, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

April 9, 2024

Date

Subscribed and Sworn to before me this 9th day of April.

Notary Public Signature

PAOLO GIANNANDREA
NOTARY PUBLIC – STATE OF MICHIGAN
COUNTY OF OAKLAND
MY COMMISSION EXPIRES 07/27/2029
Acting in the County of Oakland

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: CITAGENIX REGEN, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 39555 Orchard Hill Place, Suite 600

City: Novi State: Michigan Zip: 48375

Mailing Address (if different from physical address): N/A - same as above

City: State: Zip:

Telephone: [redacted] Website: https://www.citagenix.com/

Licensing Company Email: [redacted]

Section 2: Personal Information

First: Maik Middle: N/A Last: Rehfeldt

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Mississauga State: Ontario Zip: L5N 8G4

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ■ No * Canadian Social Insurance number (SIN)

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Toronto – Victoria University		09/83-06/87	
Address	**City**	**State**	**Zip**
73 Queen's Park Crescent	Toronto	Ontario	M5S 1K7
Diploma/Degree obtained, if any			
Bachelor of Arts			
School Name		**From - To (MM/YY – MM/YY)**	
WG City Nord		09/77-06/81	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
Matura			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/11-present	[redacted]	Toronto	Ontario	M4W 3A3
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
HANSAMED LIMITED			11/96-Present	
Business Address		**City**	**State**	**Zip**
2830 Argentia Rd., Units 7-9		Mississauga	Ontario	L5N8G4
Phone	**Title**			
1-905-813-8090	CEO			
Description of Duties				
CEO of HANSAMED LIMITED				

Business Name			From - To (MM/YY – MM/YY)	
CITAGENIX INC.			11/22-Present	
Business Address		**City**	**State**	**Zip**
4455 A Jean-Noël-Lavoie Suite 285		Laval	Quebec	H7P 4W6
Phone	**Title**			
1-905-813-8090	CEO			
Description of Duties				
CEO of CITAGENIX INC. CITAGENIX INC. is a subsidiary of HANSAMED LIMITED since Nov-2022.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maik Rehfeldt

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

16.4.2024

Date

Please have this section completed in the presence of a Notary Public.

Province
~~State~~ of Ontario, ss. City ~~County~~ of Toronto

I, Maik Rehfeldt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

16.4.2024

Date

Subscribed and Sworn to before me this 16th day of April, 2024.

[redacted]

Notary Public Signature

(Seal)

Employee List of CITAGENIX REGEN, LLC

Citagenix Regen, LLC

EIN: 98-1739050 *(taxpayer Id number)*
Business address: *39555 Orchard Hill Place, Suite 600, Novi, Michigan 48375, United States*

EMPLOYEE LIST

Name	Title, role	Email Address	Business Address
Maik Rehfeldt	CEO	[redacted]	2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada
Michael McMillan	COO		2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada
Melody Stimbert (Designated Representative)	Director, Regenerative Sales USA		39555 Orchard Hill Place, Suite 600, Novi, Michigan 48375, United States
Adriatik Mete	Manager, Global QMS & Regulatory		2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada
Renata Brelik	Director, HR & Finance		2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada
Tatiana Molina	Director, Clinical Science		2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada
Benoit Lamontagne	Director, Marketing		2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada
Hae Joeng Woo	Director, e-Commerce		2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada
Heather Zhang	QA & RA Specialist		2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada
Daniel Tomkay	QA & RA Specialist		2830 Argentia Road, Units 7-9, Mississauga, Ontario L5N 8G4, Canada

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: ITF Therapeutics LLC

Physical Address: 300 Baker Ave, Suite 280

City: Concord State: MA Zip: 01742

Mailing Address (if different from physical address): 300 Baker Avenue, Suite 280

City: Concord State: MA Zip: 01742

Telephone: 8664838479 Website: www.itftherapeutics.com

Name of Designated Representative (DR): Matthew Trudeau

Licensing Company Email: [redacted] DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies		☒ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No suppliers sold, dispensed, or distributed within the last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): ITF US HOLDING INC

Corporation/Organization Name: ITF Therapeutics, LLC

Mailing Address: 300 Baker Avenue, Suite 280

City: Concord State: MA Zip: 01742

Telephone: 8664838479 Email: [redacted]

Contact Person Name: Matthew Trudeau

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/30/24

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

ITF Therapeutics LLC
Facility Name

Matthew Trudeau
Print Name of Authorized Person Submitting Application

[redacted]
Original signature of Authorized Person (copies or stamps not accepted)

5/30/24
Date

Board Use Only	Date Received: 6/27/24	Amount: $1000-ck 1710

ITF THERAPEUTICS
ITALFARMACO

Description of Operations

ITF Therapeutics, LLC ("ITF") is a Virtual Manufacturer with a primary place of business in Concord, MA. ITF's products are manufactured by affiliate company, Italfarmaco S.A., located in Madrid, Spain, and are subsequently distributed to Specialty Pharmacies by ITF third-party logistics provider, which is licensed to ship pharmaceutical products into your state. ITF's products are **not** controlled substances regulated by the DEA.

ITF's hours of operation are 8:00 a.m. - 5:00 p.m. (Eastern Time), Monday through Friday.

Labeler Code: 11797

Contract Manufacturers:

Italfarmaco S.A.
Calle De San Rafael (P I Alcobendas) 3
Alcobendas, Madrid, Spain, 28108
FDA EIN: 3007048260

Third-Party Logistics Provider:

Cardinal Health 105 LLC dba SPS
501 Mason Road Ste 200
La Vergne, TN 37086
[redacted]

[redacted]

Asunto: Labeler Code Request Rejected

eDRLS - Electronic Drug Registration & Listing System

Current Date: 27-OCT-2023
Labeler DUNS: 469466825
Labeler Name: ITALFARMACO S.A.

This letter is to inform you that we are rejecting your Labeler Code request.

Rejection Comments

Labeler code 11797 is already assigned to your firm. Please note that the same labeler code can be used for multiple sites if they are under one company (parent, subsidiary, and/or affiliate). The labeler is usually the company that owns the brand, and the company most likely associated with the Labeler Code. If the company has multiple sites, each site must have its own DUNS and FEI number, but may operate under the same Labeler Code (11797). Just to clarify, DUNS and FEI are site-specific and labeler codes are company-specific.

CODE	LABELER DUNS	LABELER NAME	LABELER ADDRESS	AGENT NAME	AGENT DUNS
11797	428179329	Italfarmaco SPA	viale Fulvio Testi 330, Milan,20126, Italy	Chemi Pharma LLC	182471784

Parent/Headquarters (HQ/PRNT)

HQ/PRNT DUNS Number:	428179329
HQ/PRNT Company Name:	ITALFARMACO SPA
HQ/PRNT Address:	VIALE FULVIO TESTI 330
HQ/PRNT City:	MILANO
HQ/PRNT State/Province:	
HQ/PRNT Postal/Zip Code:	20126
HQ/PRNT Country:	Italy

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

An official website of the United States government Here's how you know

FDA

Home > Drug Databases > NDC > Search Result

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Current through June 24, 2024

You have searched Finished drug products

Search Results: *'italfarm'*

Back to Search Page

Keyword Search RESET

Showing 1 to 16 of 16 entries Show entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
DUVYZAT	11797-110-02	8.86mg/mL	SUSPENSION	ORAL	NDA217865	Italfarmaco SPA	11797-110	givinostat	GIVINOSTAT	HUMAN PRESCRIPTION DRUG	03/21/2024	N/A	NDA
Enoxaparin Sodium	11797-757-06	30mg/.3mL	INJECTION, SOLUTION	INTRAVENOUS; SUBCUTANEOUS	ANDA076726	Italfarmaco SpA	11797-757	Enoxaparin Sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/2021	N/A	ANDA
Enoxaparin Sodium	11797-758-06	40mg/.4mL	INJECTION, SOLUTION	INTRAVENOUS; SUBCUTANEOUS	ANDA076726	Italfarmaco SpA	11797-758	Enoxaparin Sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/2021	N/A	ANDA
Enoxaparin Sodium	11797-759-06	60mg/.6mL	INJECTION, SOLUTION	INTRAVENOUS; SUBCUTANEOUS	ANDA076726	Italfarmaco SpA	11797-759	Enoxaparin Sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/2021	N/A	ANDA
Enoxaparin Sodium	11797-760-06	80mg/.8mL	INJECTION, SOLUTION	INTRAVENOUS; SUBCUTANEOUS	ANDA076726	Italfarmaco SpA	11797-760	Enoxaparin Sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/2021	N/A	ANDA
Enoxaparin Sodium	11797-761-06	100mg/mL	INJECTION, SOLUTION	INTRAVENOUS; SUBCUTANEOUS	ANDA076726	Italfarmaco SpA	11797-761	Enoxaparin Sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/2021	N/A	ANDA
Enoxaparin Sodium	11797-762-06	120mg/.8mL	INJECTION, SOLUTION	INTRAVENOUS; SUBCUTANEOUS	ANDA076726	Italfarmaco SpA	11797-762	Enoxaparin Sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/2021	N/A	ANDA
Enoxaparin Sodium	11797-763-06	150mg/mL	INJECTION, SOLUTION	INTRAVENOUS; SUBCUTANEOUS	ANDA076726	Italfarmaco SpA	11797-763	Enoxaparin Sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/2021	N/A	ANDA
fondaparinux sodium	11797-154-06	2.5mg/.5mL	INJECTION, SOLUTION	SUBCUTANEOUS	ANDA208615	Italfarmaco S.p.A	11797-154	fondaparinux sodium	FONDAPARINUX SODIUM	HUMAN PRESCRIPTION DRUG	02/06/2019	N/A	ANDA

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
fondaparinux sodium	11797-154-09	2.5mg/.5mL	INJECTION, SOLUTION	SUBCUTANEOUS	ANDA208615	Italfarmaco S.p.A	11797-154	fondaparinux sodium	FONDAPARINUX SODIUM	HUMAN PRESCRIPTION DRUG	02/06/2019	N/A	ANDA
fondaparinux sodium	11797-155-06	5mg/.4mL	INJECTION, SOLUTION	SUBCUTANEOUS	ANDA208615	Italfarmaco S.p.A	11797-155	fondaparinux sodium	FONDAPARINUX SODIUM	HUMAN PRESCRIPTION DRUG	02/06/2019	N/A	ANDA
fondaparinux sodium	11797-155-09	5mg/.4mL	INJECTION, SOLUTION	SUBCUTANEOUS	ANDA208615	Italfarmaco S.p.A	11797-155	fondaparinux sodium	FONDAPARINUX SODIUM	HUMAN PRESCRIPTION DRUG	02/06/2019	N/A	ANDA
fondaparinux sodium	11797-156-06	7.5mg/.6mL	INJECTION, SOLUTION	SUBCUTANEOUS	ANDA208615	Italfarmaco S.p.A	11797-156	fondaparinux sodium	FONDAPARINUX SODIUM	HUMAN PRESCRIPTION DRUG	02/06/2019	N/A	ANDA
fondaparinux sodium	11797-156-09	7.5mg/.6mL	INJECTION, SOLUTION	SUBCUTANEOUS	ANDA208615	Italfarmaco S.p.A	11797-156	fondaparinux sodium	FONDAPARINUX SODIUM	HUMAN PRESCRIPTION DRUG	02/06/2019	N/A	ANDA
fondaparinux sodium	11797-157-06	10mg/.8mL	INJECTION, SOLUTION	SUBCUTANEOUS	ANDA208615	Italfarmaco S.p.A	11797-157	fondaparinux sodium	FONDAPARINUX SODIUM	HUMAN PRESCRIPTION DRUG	02/06/2019	N/A	ANDA
fondaparinux sodium	11797-157-09	10mg/.8mL	INJECTION, SOLUTION	SUBCUTANEOUS	ANDA208615	Italfarmaco S.p.A	11797-157	fondaparinux sodium	FONDAPARINUX SODIUM	HUMAN PRESCRIPTION DRUG	02/06/2019	N/A	ANDA

Previous 1 Next

1616

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

ITF THERAPEUTICS
ITALFARMACO

Company Information

Company Name: ITF Therapeutics, LLC
Address: 300 Baker Avenue, Suite 280
City, State, Zip: Concord, MA 01742
Phone: 866-483-8479
Website: www.itftherapeutics.com
[redacted]

FEIN: 36-5098020
State of Formation: Delaware
Date Incorporated: 01/29/2024
File Number: 3010806

Ownership Information

ITF Therapeutics, LLC is 100% owned by ITF US Holding Inc.

Parent Company Address: 300 Baker Ave, Suite 280, Concord, MA 01742
Parent Company Phone: 866-483-8479
Parent Company FEIN: 61-2164887

Officers

Matthew Trudeau, President (Designated Representative)
Business Address: 300 Baker Avenue, Suite 280, Concord, MA 01742
Business Phone: 866-483-8479

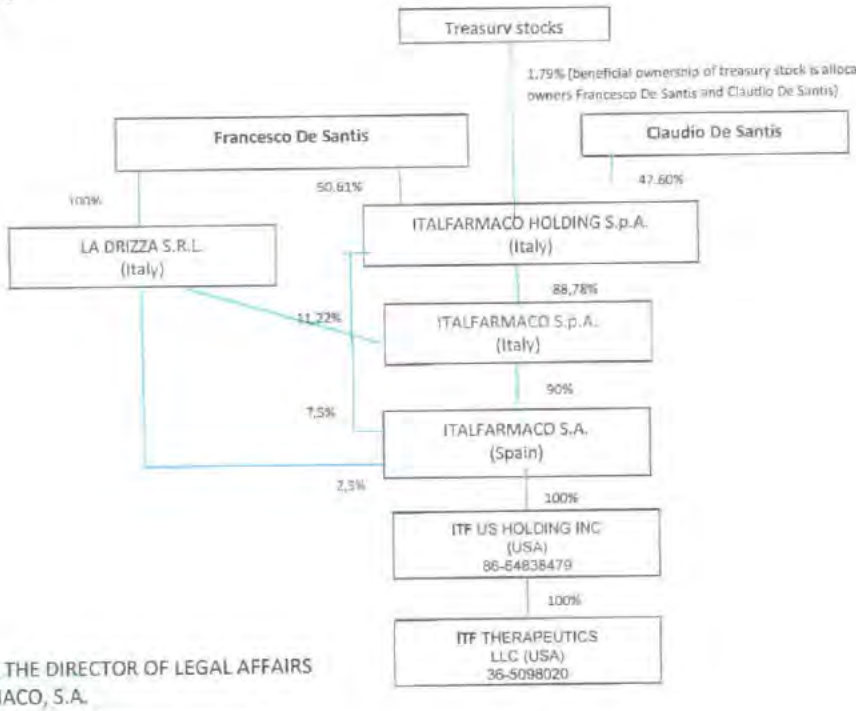
Saverio Scialdone, Secretary
Business Address: 300 Baker Avenue, Suite 280, Concord, MA 01742
Business Phone: +34 616419111

Emiliano Sala, Treasurer
Business Address: 300 Baker Avenue, Suite 280, Concord, MA 01742
Business Phone: +393480748713

ITALFARMACO

February 2024

STRICTLY CONFIDENTIAL



CERTIFIED BY THE DIRECTOR OF LEGAL AFFAIRS
OF ITALFARMACO, S.A.

[redacted]

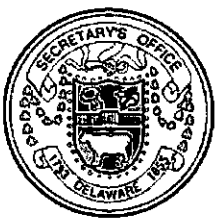
By: Jose Miguel Domenech Ciancas

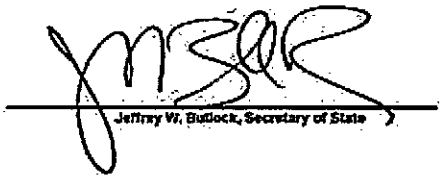
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ITF THERAPEUTICS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF APRIL, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.





3010806 8300

SR# 20241347405

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203200430

Date: 04-08-24

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF FORMATION OF 'ITF THERAPEUTICS LLC", FILED IN THIS OFFICE ON THE TWENTY-NINTH DAY OF JANUARY, A.D. 2024, AT 9:28 O`CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

3010806 8100
SR# 20240266956

Authentication: 202684514
Date: 01-29-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

DocuSign Envelope ID: 91856E13-0DBA-43CB-85C5-8051B86D23FE

CERTIFICATE OF FORMATION

OF

ITF THERAPEUTICS LLC

This Certificate of Formation of ITF Therapeutics LLC (the "**Company**") is being duly executed and filed by ITF US Holding Inc., as an authorized person, to form a limited liability company pursuant to the provisions of the Delaware Limited Liability Company Act (6 *Del. C.* §18-201, *et seq.*).

FIRST: The name of the limited liability company formed hereby is ITF Therapeutics LLC.

SECOND: The address of the registered office of the Company in the State of Delaware is c/o The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, City of Wilmington, County of New Castle, Delaware 19801.

THIRD: The name and address of the registered agent for service of process on the Company in the State of Delaware is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, City of Wilmington, County of New Castle, Delaware 19801.

State of Delaware
Secretary of State
Division of Corporations
Delivered 09:28 AM 01/29/2024
FILED 09:28 AM 01/29/2024
SR 20240266956 - File Number 3010806

DocuSign Envelope ID: 91856E13-0DBA-43CB-85C5-8051B86D23FE

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation this 29th day of January, 2024.

ITF US HOLDING INC.

[redacted]

By: _____

Name: Matthew Trudeau
Title: President

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

ITF Therapeutics LLC
300 Baker Ave, Suite 280
Concord, MA 01742

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200096

Type: Virtual Manufacturer

Issue Date: 04/16/2024

Expiration Date: 04/16/2025

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

Tel: 617-624-6000
www.mass.gov/dph

MAURA T. HEALEY
Governor
KIMBERLEY DRISCOLL
Lieutenant Governor

KATHLEEN E. WALSH
Secretary
ROBERT GOLDSTEIN, MD, PhD
Commissioner

Verification of Licensure

06/24/2024

To Whom It May Concern:

The organization named below has received the following in the Commonwealth of Massachusetts:

Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration

Name of Organization: ITF Therapeutics LLC

Registration Number: VIR200096
Registration Status: Current
Issue Date: 04/16/2024
Expiration Date: 04/16/2025
Disciplinary Actions: There are no disciplinary actions against this registration.

Registration verification may be obtained at http://checkahealthlicense.mass.gov/. The information provided in this "Verification" is based on the records maintained by the Massachusetts Bureau of Health Professions Licensure and its licensing boards. Individuals are deemed to be in good standing if their license is current and not subject to any disciplinary status on the date of issuance of the "Verification." Disciplinary status is defined as voluntary surrender, revocation, suspension or probation of a license. The "Verification" does not include information about the existence, absence, or status of complaints. To request such information, please submit a public record request to publicrecordsadmin@massmail.state.ma.us.

Traci Westgate

Traci Westgate
Director

67cc0cec-8f3e-485b-aa7e-14513e4904b2

ITF Therapeutics LLC License List

State	License Type	License Number	Issue Date	Expiration Date
Massachusetts	Virtual Manufacturer	VIR200096	4/14/2024	4/16/2025
Oregon	Manufacturer	M-0004004	5/3/2024	9/30/2024
Tennessee	Manufacturer	10436	6/12/2024	6/30/2026
West Virginia	Manufacturer	MR0552592	4/26/2024	6/30/2026

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. TIC010178

Application/License No. _____

ITF Therapeutics LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 300 Baker Avenue, Suite 280, Concord, MA 01742 (Address of Applicant/Principal), as PRINCIPAL, and Trisura Insurance Company (Surety Company), a corporation organized under the laws of the state of Oklahoma (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 210 Park Avenue Suite 1400, Oklahoma City OK 73102 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 24, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of May, 2024.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Frances Rodriguez, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Anne Potter

Witness Francesca Kazmierczak

Countersigned by:

N/A
Nevada Resident Agent

2 Stamford Plaza
Suite 1504, 281 Tresser Boulevard
Stamford, Connecticut 06901
us.surety@trisura.com

POWER OF ATTORNEY

Bond Number: TIC010178
Bond issuance date: 05/24/24

KNOW ALL MEN BY THESE PRESENTS: That **TRISURA INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Oklahoma, authorized to conduct a surety business, and having its principal place of business at 2 Stamford Plaza, Suite 1504, Tresser Boulevard, Stamford, Connecticut 06901, does hereby constitute and appoint:

Francesca Kazmierczak, Frances Rodriguez, Aklima Noorhassan, Anne Potter, Valorie Spates, Beverly A. Woolford, Sandra Diaz, Debra A. Deming, Tracy Sapere, Vilma Gonzalez

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **TRISURA INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **TRISURA INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **TRISURA INSURANCE COMPANY** at a meeting duly held on the **11th** day of **December, 2020.**

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **TRISURA INSURANCE COMPANY** have each executed and attested these presents

on this 25th day of February, 2022.

STATE OF Connecticut
County of Fairfield

Trisura Insurance Company CORPORATE SEAL

George James, Chief Underwriting Officer, Surety

On this **25th** day of **February, 2022**, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **TRISURA INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at Fairfield, Connecticut the day and year first above written.

SERENA I. SZEKELY
Notary Public, State of Connecticut
My Commission Expires 10/31/2026

Serena I Szekely seal

, a Notary Public of Connecticut

My Commission Expires: **10/31/2026**

CERTIFICATION

I, the undersigned officer of **TRISURA INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day,

Richard Grant

Richard Grant, Vice President, U.S. Surety

TO CONFIRM AUTHENTICITY OF THIS BOND OR DOCUMENT EMAIL: us.surety@trisura.com

TRISURA INSURANCE COMPANY

STATUTORY-BASIS STATEMENTS OF ADMITTED ASSETS, LIABILITIES, AND CAPITAL AND SURPLUS
AS OF DECEMBER 31, 2022

	2022
Admitted Assets	
Bonds	$ 26,997,364
Preferred stocks	1,227,994
Common stocks	155,387,143
Cash, cash equivalents and short-term investments	34,410,071
Total cash and invested assets	218,022,572
Uncollected premiums	31,081,609
Investment income due and accrued	159,142
Amounts recoverable from reinsurers	12,591,351
Receivables from subsidiaries and affiliates	2,444,666
Deferred tax asset	216,051
Total admitted assets	$264,515,391
Liabilities	
Net losses and loss adjustment expenses	$ 3,570,371
Net unearned premium reserve	6,956,020
Commissions payable, contingent commissions and other similar charges	2,508,588
Deferred commissions	2,768,334
Other expenses payable	9,281,843
Taxes, licenses and fees (excluding federal and foreign income taxes)	2,960,643
Current federal and foreign income taxes	373,294
Ceded reinsurance premiums payable	36,148,932
Funds held by company under reinsurance treaties	9,929,628
Payable to subsidiaries and affiliates	2,139,189
Provision for reinsurance	872,000
Payable for paid losses	5,734,036
Total liabilities	83,242,878
Surplus as regards policyholders	
Common stock, $140 par value, 30,000 shares authorized and issued	4,200,000
Gross paid in and contributed surplus	243,123,947
Unassigned surplus (deficit)	(66,051,434)
Total surplus as regards policyholders	181,272,513
Total liabilities & surplus as regards policyholders	$ 264,515,391

I, Eileen M Sweeney, hereby certify that I am the Executive Vice President and Chief Financial Officer of Trisura Insurance Company, a corporation duly authorized under the laws of the State of Oklahoma, licensed and engaged in the State of Oklahoma, and duly qualified to act as Surety under such laws. I further certify that I am authorized to make this certification on its behalf, and that the foregoing is a fair statement of Admitted Assets, Liabilities and Capital and Surplus as of December 31, 2022, as reflected by its books and records and as reported in its statement on file with the Oklahoma Insurance Department.

Signed and sealed this 8th day of May 2023
Attest:



Eileen M Sweeney, EVP & CFO

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ITF Therapeutics LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 300 Baker Ave, Suite 280

City Concord State MA Zip 01742

Mailing Address (if different from physical address) 300 Baker Avenue, Suite 280

City Concord State MA Zip 01742

Telephone 8664838479 Website www.itftherapeutics.com

Licensing Company Email [redacted]

Section 2: Personal Information

First Matthew Middle John Last Trudeau

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 300 Baker Ave, Suite 280

City Concord State MA Zip 01742

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northeastern University		1997-2002	
Address	City	State	Zip
360 Huntington Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
MS Molecular Biology			

School Name		From - To (MM/YY – MM/YY)	
Waltham High School		1985 - 1989	
Address	City	State	Zip
	Waltham	MA	02453
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Colby College		1991 - 1994	
Address	City	State	Zip
	Waterville	ME	04901
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/12 - present	[redacted]	Concord	MA	01742
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
ITF Therapeutics LLC			01/24 - current
Business Address	**City**	**State**	**Zip**
300 Baker Avenue, Suite 280	Concord	MA	01742
Phone	**Title**		**Number of Employed Hours**
8664838479	President		40/wk
Description of Duties			
See Resume			

Business Name			From - To (MM/YY – MM/YY)
Bartlett Hill Consulting			01/23 - 12/23
Business Address	**City**	**State**	**Zip**
119 Bartlett Hill Rd	Concord	MA	01742
Phone	**Title**		**Number of Employed Hours**
6174175142	President & Founder		
Description of Duties			
See Resume			

Business Name			From - To (MM/YY – MM/YY)
VBL Therapeutics			01/22-08/22
Business Address	**City**	**State**	**Zip**
	Modi'in	Israel	
Phone	**Title**		**Number of Employed Hours**
NA	Chief Commercial Officer		40/wk
Description of Duties			
See Resume			

Business Name			From - To (MM/YY – MM/YY)
Bluebird Bio			04/16-08/21
Business Address	**City**	**State**	**Zip**
840 Memorial Dr # 13	Cambridge	MA	02139
Phone	**Title**		**Number of Employed Hours**
(617) 491-5601	Head, US Business		40/wk
Description of Duties			
See Resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/30/24

Date

I, Matthew Trudeau, **certify that as the designated representative for**

ITF Therapeutics LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MJ I am at least 21 years of age;
3. MJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Matthew Trudeau

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/30/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Trudeau

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/30/24

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Middlesex

I, Matthew Trudeau, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

5/30/24

Date

Subscribed and Sworn to before me this 30 day of May, 2030.

R. Lee Fields

Notary Public Signature

R. LEE FIELDS
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS
MY COMMISSION EXPIRES FEB 8 2030

MATTHEW J. TRUDEAU

CONCORD, MA 01742 | [redacted] | [redacted]

CHIEF COMMERCIAL OFFICER & BUSINESS OPERATIONS LEADER

Strategic and operational leader with demonstrated ability to build and lead coalitions to solve complex problems and achieve excellence in delivery of patient and shareholder value. Experienced leading all aspects of commercialization practice at small and mid-cap biotech organizations to bring life-changing therapies to patients in need. Designer and builder of insight-driven business strategy, fit-for-purpose operating structures, and high-quality mission-focused teams.

Core Competencies:

- Cross-functional leadership
- Cross-cultural leadership
- Enterprise transformation
- Change management
- Product launch & lifecycle planning
- Portfolio & new product planning
- Oncology, Rare, Neurology, Hematology
- Gene therapy, biologics, diagnostics
- Investor engagement
- Operational effectiveness
- Enterprise system & process design
- Partner & alliance management

EXPERIENCE

ITF Therapeutics, Concord, MA — 1/2024 – Present

President

Reporting to the Chief Executive Officer of the Italfarmaco group. Assembled experience cross-functional leadership team, established capability ecosystem, and created new business infrastructure to enable launch of innovative asset for Duchenne Muscular Dystrophy. Accountable for all aspects of US P&L. President of ITF Therapeutics Board of Directors.

BARTLETT HILL CONSULTING, Concord, MA — 1/2023 – 12/2023

President & Founder

Independent consultant helping clinical-stage biopharma organizations in a consulting or fractional leadership capacity to address commercialization questions, align strategic direction, and implement operations at all phases of product development.

- Fractional CCO for late-clinical-stage ocular disease products company. Supporting executive team to build product strategy, plan US commercialization roadmap, and design go-to-market partnership model.
- Designing OUS commercialization strategy for late-clinical-stage oncology product company. Supporting executive team to assess OUS commercialization potential and design optimal operating model.

VBL THERAPEUTICS, Modi'in Isreal — 1/2022 – 8/2022

Chief Commercial Officer

Reported to the Chief Executive Officer. Design and implement a commercialization practice at clinical stage organization to launch first-in-class anti-cancer adenovirus agent with anticipated launch indication for platinum resistant ovarian cancer and lifecycle expansion into additional solid tumor diseases. Role eliminated following demonstration of futility in phase 3 trial.

- Led asset strategy and valuation work. Aligned Board of Directors on asset value, revenue forecast ranges, and a range of value creation strategies including direct to market options, partner models, and M&A considerations.
- Led change management with an executive leadership team that was naive to commercialization practice. Led establishment of integrated business goals, defined company launch strategy, and led enterprise transformation.
- Partnered with CFO and CEO to develop and execute investor engagement ahead of planned capital raise.

BLUEBIRD BIO, Cambridge, MA — 4/2016 – 8/2021

Head, US Business (3/2020 – 8/2021)

Reported to the Chief Commercial Officer. Led cross-functional US leadership team to design, plan, and execute company-first gene therapy product launches in the US market with forecasted annual revenue >$1B. Accountable for US P&L, cross-functional goal-setting, capability & team development, and performance management. Role eliminated due to restructuring.

- Designed and built architecture for *ex-vivo* gene therapy product commercialization including innovative market-access and value strategy, demand generation strategy, care delivery strategy, and all aspects of go-to-market structure.

Vice President, US Marketing (10/2019 – 3/2020)

Reported to the US Business Head. Led a team of marketing professionals for first-in-class *ex vivo* gene therapies with responsibility for marketing strategy, tactical mix, and performance management for physician, patient, and payer segments.

- Oversaw development and implementation of insight-driven pre-launch market disruption strategies that increased disease and company awareness as measured by stakeholder digital engagement scores and progress to defined market metrics.

Vice President, Global Commercial Operations (10/2017 – 10/2019)

Reported to the Chief Commercial Officer. Recruited and developed a team of eleven leaders who designed fit-for-purpose commercialization platforms, processes, and capabilities to enable Bluebird Bio's first commercial launches.

- Developed and deployed integrated launch architecture, digital engagement and analytics capability, field enablement and analytics platform, marketing operations infrastructure, and first-in-class gene therapy customer model.

Senior Director, Customer Models (4/2016 – 10/2017)

Reported to the Senior Vice President, Commercial. Led design of insight-driven customer model for launch of novel *ex vivo* gene therapy product including all aspects of care delivery and stakeholder engagement strategies. Led development of relevant enterprise-level systems and processes to meet manufacturing and customer model design requirements.

- Achieved C-suite endorsement and oversaw implementation of go-to-market models including role alignment, service platform and business process design, data strategy and architecture, and integrated manufacturing and supply plans.

BIOGEN, Singapore & Cambridge MA 9/2010 – 3/2016

Director, International Commercial Operations (7/2015 – 3/2016)

Reported to Senior Vice President, Japan, Australia, and Emerging Markets. Led team of four commercial operations leaders to manage business-critical processes and establish excellence in commercial operations to enable local selling capabilities.

- Designed and implemented business governance, led implementation of next-generation commercial IT systems to enable and measure impact, established customized field training platform, and managed demand forecasting to ensure supply.

Head, APAC Region (1/2014 – 7/2015)

Reported to Vice President, Distributor Business. Led cross-functional regional team to transition APAC operations from an affiliate to a distributor model. Accountable for regional P&L. Served as Director, Board of Directors of the Singapore affiliate.

- Led cross-functional, cross-cultural, cross-alliance team to prepare and execute eight commercial launches and 18 regulatory filings over twelve months. Doubled the number of patients on therapy and exceeded regional revenue goals.
- Advanced one small molecule and four biologics through China clinical development leading to CTA approval.

Director, Global Marketing (9/2010 – 12/2013)

Reported to Senior Director, TYSABRI Global Marketing. Led design and implementation of an innovative risk management scheme including value chain and go-to-market design, brand positioning and messaging, and communication platform.

- Implemented comprehensive risk-stratification scheme that enabled 12.5%-unit growth on mature $1.4B product. Achieve all operational and strategic metrics including value chain development and customer-level implementation across regions.

GENZYME CORPORATION, Cambridge, MA 9/1996 – 9/2010

Senior Director, US and Global Marketing, Biosurgery Division (9/2003 – 9/2010)

Reported to Vice President, General Manager. Promoted through marketing roles of increasing US and Global scope for a surgical biomaterial & cell therapy portfolio. Hired and developed a team of six marketing leaders.

- Grew Global and US revenue to $165M (20% five-year CAGR) and $100M (19% five-year CAGR), respectively, by deepening penetration in the US, Japan, and EU, and by expanding global reach including build-out of APAC business.

Sales Manager, Research Products and Clinical Diagnostics Divisions (9/1996 – 12/2002)

Progressed through Sales roles of increasing responsibility and contribution. Sustained top-line growth by managing and growing direct accounts, distribution partners, and industry OEM partners.

HARVARD MEDICAL SCHOOL, Boston, MA 7/1994 – 9/1996

Research Laboratory Manager, Pathology Department, Managed all operational aspects of medical research laboratory. Published author.

EDUCATION

Greater Boston Executive Program, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, Cambridge, MA
Master of Science, Molecular Biology, NORTHEASTERN UNIVERSITY, Boston, MA
Bachelor of Arts, *with distinction,* Biochemistry, COLBY COLLEGE, Waterville, ME



ITF Therapeutics, LLC
300 Baker Avenue
Suite 280
Concord, MA 01742

Employee List

Matthew Trudeau

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Pangea Pharmaceuticals, LLC

Physical Address: 201 Union Lane Suite B

City: Brielle State: NJ Zip: 08730

Mailing Address (if different from physical address): 642 NE 3rd Ave

City: Fort Lauderdale State: FL Zip: 33304

Telephone: 18662726432 Website: www.pangeapharm.com

Name of Designated Representative (DR): Stephen Flood

Licensing Company Email: info@pangeapharm.com DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Prescription Drug Products	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

06/17/24

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): _____

Corporation/Organization Name: Pangea Pharmaceuticals, LLC

Mailing Address: 201 Union Lane Suite B

City: Brielle State: NJ Zip: 08730

Telephone: 9543489455 Email: info@pangeapharm.com

Contact Person Name: Anthony LaViola

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Pangea Pharmaceuticals, LLC

Facility Name

Anthony LaViola

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

06/17/24

Date

Board Use Only	Date Received: 6/18/24	Amount: $1000 - CK 5538

From: edrls@fda.hhs.gov
Subject: Labeler Code Request Approved
Date: December 15, 2020 at 6:22 PM
To: alaviola@pangeapharm.com

eDRLS - Electronic Drug Registration & Listing System

Current Date: 15-DEC-2020
Labeler DUNS: 117751012
Labeler Name: Pangea Pharmaceuticals LLC.
Labeler Code Assigned: 81279

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

PANGEA
PHARMACEUTICALS

List of Officers and Directors

Company: Pangea Pharmaceuticals, LLC - FEIN # 83-4468762

Anthony LaViola
[redacted]Las Olas Way, APT 3802
Fort Lauderdale, FL 33301
[redacted]

Stephen Flood
[redacted]Sycamore Lane
Brielle, NJ 08730
[redacted]

PANGEA
PHARMACEUTICALS

Ownership

Company: Pangea Pharmaceuticals, LLC - FEIN # 83-4468762

Managing Partners:

Anthony LaViola Member – 50%
[redacted]as Olas Way, APT 3802
Fort Lauderdale, FL 33301
[redacted]

Stephen Flood Member – 50%
[redacted]Sycamore Lane
Brielle, NJ 08730
[redacted]

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PANGEA PHARMACEUTICALS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF JANUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PANGEA PHARMACEUTICALS, LLC" WAS FORMED ON THE EIGHTEENTH DAY OF APRIL, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7380686 8300

SR# 20240113818

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202586925

Date: 01-12-24

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0750713

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

201 UNION LN, STE B BRIELLE, NJ 08730-

Reg. No.
5006007

PANGEA PHARMACEUTICALS, LLC
201 UNION LN, STE B
BRIELLE, NJ 08730-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 6/17/2024

Registration Number: 5006007 **Registered as:** Wholesale

Name: PANGEA PHARMACEUTICALS, LLC

DBA:

Address: 201 UNION LN, STE B, BRIELLE, NJ 08730

Original Issue Date: 11/15/2021 **Expiration Date:** 01/31/2025

Current Issue Date: 01/09/2024

Disciplines: No

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 2341217

Application/License No. _____

Pangea Pharmaceuticals, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 201 Union Lane Suite B, Brielle, NJ 08730 (Address of Applicant/Principal), as PRINCIPAL, and Swiss Re Corporate Solutions America Insurance Corporation (Surety Company), a corporation organized under the laws of the state of Missouri (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1200 Main Street, Suite 800, Kansas City, MO 64105-2478 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 15, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of March, 2024.

Pangea Pharmaceuticals, LLC
APPLICANT/PRINCIPAL COMPANY

Authorized Representative

Swiss Re Corporate Solutions America Insurance Corporation
SURETY

Surety Company's Representative

Donna M. Chiancone, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Sunil K. Agarwal

Witness Renay Barnes

SIGNED and SEALED in the presence of:

Witness Lori N. Baybutt, Witness to Surety

Witness Kevin Baybutt, Witness to Surety

Countersigned by:

Nevada Resident Agent NV Non-Resident License # 545412
Donna M. Chiancone

Posted February 20, 2020

SWISS RE CORPORATE SOLUTIONS

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION ("SRCSAIC")
SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION ("SRCSPIC")

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT SRCSAIC, a corporation duly organized and existing under laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, and SRCSPIC, a corporation organized and existing under the laws of the State of Missouri and having its principal office in the City of Kansas City, Missouri, each does hereby make, constitute, and appoint:

DONNA M. CHIANCONE, TRAVIS W. SHAFFER, LORI N. BAYBUTT, KATHLEEN A. PETERSEN,
and LAURA A. RICKETT
JOINTLY OR SEVERALLY

Its true and lawful Attorney(s)-in-Fact, to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

TWO HUNDRED MILLION ($200,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both SRCSAIC and SRCSPIC at meetings duly called and held on the 9th of May 2012:

"RESOLVED, that any two of the President, any Managing Director, any Senior Vice President, any Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is, authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Corporation bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Corporation; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Corporation may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Corporation when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION CORPORATE SEAL 1973 MISSOURI

SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION CORPORATE SEAL MISSOURI

By_____
Erik Janssens, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC

By_____
Gerald Jagrowski, Vice President of SRCSAIC & Vice President of SRCSPIC

IN WITNESS WHEREOF, SRCSAIC and SRCSPIC have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers this 10TH day of NOVEMBER, 2022

Swiss Re Corporate Solutions America Insurance Corporation
Swiss Re Corporate Solutions Premier Insurance Corporation

State of Illinois
County of Cook ss

On this 10TH day of 15th, 20 22, before me, a Notary Public personally appeared Erik Janssens, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC and Gerald Jagrowski, Vice President of SRCSAIC and Vice President of SPCSPIC, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

OFFICIAL SEAL
CHRISTINA MANISCO
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires March 28, 2026

Christina Manisco
Christina Manisco, Notary

I, Jeffrey Goldberg, the duly elected Senior Vice President and Assistant Secretary of SRCSAIC and SRCSPIC, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said SRCSAIC and SRCSPIC, which is still in full force and effect.
IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 15th day of March, 20 24

Jeffrey Goldberg, Senior Vice President &
Assistant Secretary of SRCSAIC and
SRCSPIC

Swiss Re
Corporate Solutions
SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION

1450 American Lane, Suite 1100, SCHAUMBURG, ILLINOIS 60173
800/338-0753

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION
A Missouri Corporation

BALANCE SHEET AS OF DECEMBER 31, 2022
(Statutory Basis)

Valuation of securities on National Association of Insurance Commissioner Basis

ASSETS		**LIABILITIES**	
Cash	424,718,741	Reserve for Unearned Premiums	149,350,540
Bonds	797,801,222	Reserve for Losses and Loss Adjustment Expenses	235,835,273
Common Stock	315,720,039	Funds Withheld	92,137,049
Other Invested Assets	34,744	Taxes and Other Liabilities	429,886,411
Other Admitted Assets	385,652,521	Surplus	1,016,717,994
TOTAL ADMITTED ASSETS	1,923,927,267	**TOTAL LIABILITIES & POLICYHOLDERS' SURPLUS**	1,923,927,267

The undersigned, being duly sworn, says: That he is Vice President of Swiss Re Corporate Solutions America Insurance Corporation, Kansas City, Missouri that said company is a corporation duly organized, existing by virtue of the Laws of the State of Missouri and that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress approved, July 1947 6 U.S.C. sec. 6-13; and that to the best of his knowledge and belief the above statement is a full, true and correct statement of the financial condition of the said Company on the 31st day of December, 2022

Gerald Jagrowski, Vice President
Swiss Re Corporate Solutions America Insurance Corporation

Subscribed and sworn before me,
this 18th day of April, 2023

Notary Public

Official Seal
Kenneth Michael Mesiny
Notary Public State of Illinois
My Commission Expires 10/19/2026

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Pangea Pharmaceuticals, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 201 Union Lane Suite B

City: Brielle State: NJ Zip: 08730

Mailing Address (if different from physical address): 201 Union Lane Suite B

City: Brielle State: NJ Zip: 08730

Telephone: 908 675-7867 Website: www.pangeapharm.com

Licensing Company Email: info@pangeapharm.com

Section 2: Personal Information

First: Stephen Middle: Last: Flood

Alias(es, nicknames, name changes, etc.):

Date of Bir[redacted] SSN or ITI[redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addres[redacted] Sycamore Lane

City: Brielle State: NJ Zip: 08730

Telephone: 908 675-7867 Email: SFlood@Pangeapharm.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Catawba College, North Carolina		1981 - 1985	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
B.S			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/16 - Present	[redacted]ycamore Lane	Brielle	NJ	08730
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Pangea Pharmaceuticals, LLC			06/19	
Business Address		**City**	**State**	**Zip**
201 Union Lane, Suite B		Brielle	NJ	08730
Phone	**Title**		**Number of Employed Hours**	
908 675-7867	Co-Founder		10000	
Description of Duties				
Co-founder take all business and operations decisions				

Business Name			From - To (MM/YY – MM/YY)	
Seton Pharmaceuticals			2003-2016	
Business Address		**City**	**State**	**Zip**
1967 Hwy 34, Suite 103		Wall	NJ	07719
Phone	**Title**		**Number of Employed Hours**	
			22000	
Description of Duties				
Added a full line generic company from within, Seton Pharmaceuticals. Seton was a direct vendor for generic products within all the major points of distribution, i e chain, wholesalers, GPO's, etc. Seton successfully marketed its' own ANDA'				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8 Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	**Governing**, licensing, **Arresting** Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/24/24
Date

I, Stephen Flood, certify that as the designated representative for

Pangea Pharmaceuticals, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. Yes I am at least 21 years of age;
3. Yes I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. Yes I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. Yes I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. Yes I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. Yes I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Stephen Flood

Print Name (First, Last)

Original **Signature (electronic, copies or stamps not accepted)**

6/26/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Stephen Flood

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/26/24

Date

Please have this section completed in the presence of a Notary Public.

State of newjersey, ss. County of monmouth

I, Stephen Flood, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/26/2024

Date

Subscribed and Sworn to before me this 26th day of June

Notary Public Signature

ALICIA M ZAITA
Notary Public
State of New Jersey
My Commission Expires Dec. 06, 2026
I.D.# 2415272

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Pangea Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 201 Union Lane Suite B

City: Brielle State: NJ Zip: 08730

Mailing Address (if different from physical address): 642 NE 3rd Ave

City: Fort Lauderdale State: FL Zip: 33304

Telephone: 18662726432 Website: www.pangeapharm.com

Licensing Company Email: info@pangeapharm.com

Section 2: Personal Information

First: Anthony Middle: Last: LaViola

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] LAS OLAS WAY APT. NO. 3802

City: FORT LAUDERDALE State: FL Zip: 33301

Telephone: [redacted] Email: ALaviola@Pangeapharm.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
San Diego State University			2006 - 2008	
Address		City	State	Zip
Diploma/Degree obtained, if any				
Master of Science in Regulatory Affairs				

School Name			From - To (MM/YY – MM/YY)	
Temple University			2002 - 2006	
Address		City	State	Zip
Diploma/Degree obtained, if any				
Bachelor of Science in Chemistry				

School Name			From - To (MM/YY – MM/YY)	
Scranton Preparatory School			1998- 2002	
Address		City	State	Zip
1000 Wyoming Avenue		Scranton	PA	18509
Diploma/Degree obtained, if any				
High School				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/22 - Present	[redacted] AS OLAS WAY APT. NO. 3802	Fort Lauderdale	FL	33301
07/19 - 03/22	[redacted] AS OLAS WAY APT. NO. 3306	Fort Lauderdale	FL	33301
02/14 - 07/19	[redacted] SE 6th ST	Deerfield Beach	FL	33341
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Pangea Pharmaceuticals, LLC			06/19
Business Address	**City**	**State**	**Zip**
642 NEn 3rd AVE	Fort Lauderdale	FL	33301
Phone	**Title**		
9543489455	Co-Founder & CEO		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Pharmobedient Consulting, LLC			03/14-05/19
Business Address	**City**	**State**	**Zip**
	Fort Lauderdale	FL	33304
Phone	**Title**		
Description of Duties			
Regulatory Affairs Certified (RAC).Lead a full service regulatory affairs consulting firm with knowledge and expertise in chemistry, manufacturing and controls (CMC); quality assurance and compliance for pharmaceuticals products			

Business Name			From - To (MM/YY – MM/YY)
Boca Pharmacal			01/07-03/14
Business Address	**City**	**State**	**Zip**
	Coral Sprins	FL	
Phone	**Title**		
	Director, Regulatory Affairs		
Description of Duties			
• Develop and oversee regulatory strategy • Manage regulatory filings including scheduling, oversight, drafting, preparation and submission to regulatory authorities for all products • Lead interactions with FDA and other agencies			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

06/17/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anthony LaViola

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/17/24

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Anthony LaViola, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/17/24

Date

Subscribed and Sworn to before me this 17th day of June 24

Notary Public Signature

RENAY BARNES
MY COMMISSION # HH 436550
EXPIRES: August 22, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Pangea Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 201 Union Lane, Suite B

City: Brielle State: NJ Zip: 08730

Mailing Address (if different from physical address): 642 NE 3RD AVE

City: Fort Lauderdale State: FL Zip: 33304

Telephone: 18662726432 Website: www.pangeapharm.com

Licensing Company Email: info@pangeapharm.com

Section 2: Personal Information

First: Stephen Middle: Last: Flood

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Sycamore Lane

City: Brielle State: NJ Zip: 08730

Telephone: [redacted] Email: SFlood@Pangeapharm.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Catawba College, North Carolina			1981-1985
Address	City	State	Zip
Diploma/Degree obtained, if any			
B.S.			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/16 - Present	[redacted] Sycamore Lane	Brielle	NJ	08730
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Pangea Pharmaceuticals, LLC			06/19 - Present
Business Address	**City**	**State**	**Zip**
201 Union Lane, Suite B	Brielle	NJ	08730
Phone	**Title**		
(908) 675-7867	Co- Founder		

Description of Duties

Co-founder take all business and operations decisions

Business Name			From - To (MM/YY – MM/YY)
Seton Pharmaceuticals			2003-2016
Business Address	**City**	**State**	**Zip**
1967 Hwy 34, Suite 103	Wall,	NJ	07719
Phone	**Title**		

Description of Duties

Added a full line generic company from within, Seton Pharmaceuticals. Seton was a direct vendor for generic products within all the major points of distribution, i.e. chain, wholesalers, GPO's, etc. Seton successfully marketed its' own ANDA'

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

06/12/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Stephen Flood

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Morris

I, Stephen Flood, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/12/2024

Date

Subscribed and Sworn to before me this 12th day of June, 2024

Notary Public Signature

ANNE SOLBAN
Notary Public, State of New Jersey
My Commission Expires Jan 14, 2026

(Seal)

PANGEA
PHARMACEUTICALS

List of Employees

Company: Pangea Pharmaceuticals, LLC - FEIN # 83-4468762

Anthony LaViola CEO
Phone # 866-272-6432 X 102

Stephen Flood Principal
Phone # [redacted]

Sunil Agarwal Controller
Phone # 866-272-6432 X 101

Sanjeev Nooty Director of Operations
Phone # 866-272-6432 X 103

Pangea Pharmaceuticals, LLC
201 Union Lane, Ste B
Brielle, NJ 08730

Ofc: (866) 272-6432
Fax: (413) 556-6632

Website: www.pangeapharm.com
Email: info@pangeapharm.com

PANGEA
PHARMACEUTICALS

List of Indebtedness as of March 13, 2024

Company: Pangea Pharmaceuticals, LLC - FEIN # 83-4468762

Valley Bank

301 East Las Olas Blvd. Suite 250,

Fort Lauderdale, FL 33301

Pangea Pharmaceuticals, LLC
201 Union Lane, Ste B
Brielle, NJ 08730

Ofc: (866) 272-6432
Fax: (413) 556-6632

Website: www.pangeapharm.com
Email: info@pangeapharm.com

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PUBLIC HEALTH AND FOOD PROTECTION PROGRAM
P.O. BOX 369, TRENTON, NJ 08625-0369
609-826-4935

REPORT OF INSPECTION

Assignment No **17302**
Inspection End Date **10/12/2021**

Registration #	Category	Inspection Type	Evaluation
5006007	**Wholesale Drug/Medical Device**	**Initial**	**Satisfactory**

Name of Owner or Corporation	Trade Name	Activity
Pangea Pharmaceuticals, LLC	**Same**	**Office Only**

Establishment Street Address	City	ZIP	County
201 Union Lane, Suite B	**Brielle**	**08730**	**Monmouth**

Establishment Mailing Address (if different)	Phone Number	Fax Number
642 NE 3rd Ave, Fort Lauderdale, FL 33304	**954-348-9455**	

Name and Title of Inspecting Official	REHS Lic. #	Operational Status	Embargo	Reinspect on or After
Annie Pullockaran, REHI 1	**B-150656**	**Pre-Operational**	**------**	

Name and Title of Designated Representative	Email
Anthony Laviola, Managing Partner	**alaviola@pangeapharm.com**

Products
☒ Prescription Drugs ☒ OTC Drugs ☐ Class I Medical Devices ☐ Class II Medical Devices ☐ Class III Medical Devices
☐ API ☐ Veterinary Drugs ☒ No Products Stored/Handled Onsite

TIME/ACTIVITY REPORT (1-TRAVEL, 2-INSPECTION, 3-ADMINISTRATION, 4-PERSONAL) TOTAL HOURS: 05.00

DATE	CODE	BEGIN	END	CODE	BEGIN	END	CODE	BEGIN	END
10/12/2021	1	08:45	10:00	2	10:00	11:45	1	11:45	13:15
10/12/2021	3	15:30	16:00						

		YES	NO	N/A
	N.J.A.C. 8:21-3A.7 Personnel Requirements			
	Personnel employed by a wholesale distributor have appropriate education and/or experience to assume responsibility for positions related to compliance with State registration requirements	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.8 Facility *Facilities at which drugs are stored, warehoused, handled, held, offered, marketed or displayed:*			
(a) 1	Of suitable size and construction to facilitate cleaning, maintenance, and proper operations	☒	☐	☐
(a) 2	Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions	☐	☐	☒
(a) 3	Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened	☐	☐	☒
(a) 4	Maintained in a clean and orderly condition	☒	☐	☐
(a) 5	Free from infestation by insects, rodents, birds, or vermin of any kind	☒	☐	☐
Note				

		YES	NO	N/A
	N.J.A.C. 8:21-3A.9 Security			
(a)	Facility is secured from unauthorized entry	☒	☐	☐
(a) 1	Access from outside premises is kept to a minimum and is well controlled	☒	☐	☐
(a) 2	The outside perimeter of the premises is well-lighted	☒	☐	☐
(a) 3	Entry into areas where drugs are held shall be limited to authorized personnel	☐	☐	☒
(b)	All facilities are equipped with an alarm system to detect entry after hours	☒	☐	☐
(c)	Facilities are equipped with a security system that provides suitable protection against theft and diversion. When applicable, the security system provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.10 Storage			
(a)	All drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, of the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).	☐	☐	☒
(b)	If no storage requirements are established for a drug, the drug is held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected	☐	☐	☒
(c)	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs are utilized to document proper storage of drugs	☐	☐	☒
(d)	For prescription drugs a record is maintained that includes the date, time, thermometer temperature, and the initials of the person recording the data	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.11 Examination of Materials			
(a)	Upon receipt, each outside shipping container is visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination is adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	☐	☐	☒

		YES	NO	N/A
(b)	Each outgoing shipment is carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.12 Returned, Damaged and Outdated Drugs			
(a)	Outdated, damaged, deteriorated, misbranded, or adulterated drugs are quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier	☐	☐	☒
(b)	Drugs whose immediate or sealed outer or sealed secondary containers have been opened or used are identified as such, quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier	☐	☐	☒
(c)	If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.13 Recordkeeping			
(a)	Inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs are maintained	☒	☐	☐
(a) 1	Source of drugs, name and principal address of the seller or transferor, and address from which drugs were shipped are maintained	☒	☐	☐
(a) 2-3	Identity and quantity of drugs received and distributed/disposed, date of receipt and distribution, disposal.	☒	☐	☐
(a) 5	A complete and accurate annual record of all stock of drugs on hand.	☒	☐	☐
(d)	An ongoing listing of all retail and wholesale establishments with whom they do business.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.14 Due Diligence *Firm is performing due diligence of other wholesale establishments with whom they do business, which requires that prior to the initial purchase or acquisition of drugs from another wholesale distributor, a wholesale distributor shall obtain the following information from the selling wholesale distributor:*			
(a) 1	Copies of all state and Federal regulatory licenses and registrations	☒	☐	☐
(a) 2	The wholesale distributor's most recent facility inspection reports	☒	☐	☐
(a) 3	A list of other names under which the wholesale distributor is doing business or by which the wholesale distributor was formerly known	☒	☐	☐

		YES	NO	N/A
(a) 4	A list of corporate officers and managerial employees and designated representatives	☒	☐	☐
(a) 5	A verification of the selling wholesale distributor's status as an authorized distributor of record, if applicable.	☒	☐	☐
(b)	At least annually, a wholesale distributor that purchases prescription drugs from another wholesale distributor updates the information set forth in (a) 1-5 above.	☒	☐	☐
(c)	No purchases were placed from any storage facility, manufacturer or wholesale distributor not having a current license or registration within the jurisdiction of the establishment location from where product is purchased.	☒	☐	☐
(d)	No purchase or acquisition has been made from a firm that has not provided complete information as set forth in (a) 1-5 above.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.15 Availability of Records and Inventories			
(a)	Records and inventories, including those related to salvage and reprocessing, are made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation	☒	☐	☐
(b)	Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means are readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable are made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.16 Policies and Procedures			
(a)	Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of drugs	☒	☐	☐
(a)	Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories	☒	☐	☐
(a) 1	Firm has a procedure where oldest stock is distributed first.	☒	☐	☐
(a) 2	Firm has a procedure for handling recalls/withdrawals of drugs.	☒	☐	☐
(a) 3	Firm has a procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster	☒	☐	☐
(a) 4	Firm has a procedure for handling return of outdated drugs; segregation and written documentation of disposal, by either returning the drug to the manufacturer or destruction of the drug. This documentation shall be maintained for 2 years after disposition of the outdated drugs.	☒	☐	☐

		YES	NO	N/A
Note				
	N.J.A.C. 8:21-3A.17 List of Responsible Persons			
	A current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of prescription drugs is maintained at the firm	☒	☐	☐
	Description of duties and qualifications of personnel is maintained at the firm	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.19 Salvage; Reprocessing			
	Salvaging and reprocessing operation is in compliance with 21 CFR 207, 210, 211	☒	☐	☐
Note				

Note: This is an initial inspection of the firm.

Upon my arrival at the facility, I met with Mr. Anthony Laviola, Managing Partner, and he provided all the information for this report. This firm operates as a Virtual manufacturer and distributor of Ophthalmic injectable drugs. The firm does not have any commercial products in the market at the time.

Janice Pulbotaran

Inspecting Official

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: ENDEAVOR DISTRIBUTION, LLC

Physical Address: 7400 PLAZA MAYOR BLVD., SUITE 200

City: OKLAHOMA CITY State: OK Zip: 73149

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 405-839-7891 Website: n/a

Name of Designated Representative (DR): Karlo Valerio

Licensing Company Email: karlo.valerio@endeavordistribution.com DR Email: karlo.valerio@endeavordistribution.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Amerisource Bergen
Address: 501 Patriot Parkway City: Roanoke State: TX Zip: 76262
Name: Seqirus USA
Address: 25 Deforest Ave, Suite 200 City: Summit State: NJ Zip: 07901
Name: McKesson
Address: 6555 State Hwy 161 City: Irving State: TX Zip: 75039
Name: N/A (we only have those 3)
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Pharmacorr Holdings, LLC
Corporation/Organization Name: Pharmacorr Holdings, LLC
Mailing Address: 7400 Plaza Mayor Blvd.
City: Oklahoma City State: OK Zip: 73149
Telephone: 888-321-7774 Email: adam.curling@pharmacorr.com
Contact Person Name: Adam Curling

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Endeavor Distribution, LLC

Facility Name

Karlo Valerio

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/17/2024

Date

Board Use Only	Date Received: 6/26/24	Amount: $1000-CK 300123

NABP ACCREDITED
DRUG DISTRIBUTOR

Endeavor Distribution, LLC

located at

7400 Plaza Mayor Blvd., Ste 200, Oklahoma City, OK 73149

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

06/14/2022 - 06/13/2025
Period of Accreditation

Verified 8/12/24 MS

ENDEAVOR DISTRIBUTION

Re: Endeavor Distribution, LLC – Officers

The current slate of officers for Endeavor Distribution, LLC are as listed below.

Name: Jason Sievers	**Title:** Controller
Address: [redacted] Road, St. Jacob, IL 62281	
	DOB: [redacted]
Name: Adam Curling	**Title:** Vice President of Pharmacy Operations
Address: [redacted] St., Oklahoma City, OK 73162	
	DOB: [redacted]
Name: Pharmacorr Holdings, LLC	**Title:** Chief Manager and Sole Member
Business Address: [redacted] Plaza Mayor Blvd., Oklahoma City, OK 73149	
Pharmacorr Holdings, LLC owns 100% of Endeavor Distribution, LLC	

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ENDEAVOR DISTRIBUTION, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIFTH DAY OF JUNE, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7387520 8300

SR# 20242972601

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203786868

Date: 06-25-24

OKLAHOMA
State Board of Pharmacy

2920 N Lincoln Blvd, Suite A, Oklahoma City, OK 73105
Marty Hendrick, Pharm.D., D.Ph., Executive Director
pharmacy@pharmacy.ok.gov • www.pharmacy.ok.gov
Phone: 405.521.3815 • Fax: 405.521.3758

June 13, 2024

CERTIFIED LICENSE VERIFICATION

Name:	ENDEAVOR DISTRIBUTION LLC
Address:	7400 PLAZA MAYOR BLVD STE 200, OKC, OK 73149
License Number:	1-W-5896
Date Issued:	05/30/2019
Expiration Date:	05/31/2025
License Type:	WHOLESALE
Disciplinary Action:	NONE
Licensure Status:	ACTIVE
Date of Last Inspection:	04/05/2023
Licensed By:	OKLAHOMA STATE BOARD OF PHARMACY
Verification Date:	June 13, 2024
Verified By:	Marquise Robertson (MARQUISE ROBERTSON)
Title:	ADMINISTRATIVE PROGRAM OFFICER II
SEAL:	OKLAHOMA STATE BOARD OF PHARMACY

A Constitutional Board Established in 1907

President	Vice-President	Member	Member	Member	Member
Jim Spoon, D.Ph. *Sand Springs*	Justin Wilson, D.Ph. *Norman*	Mark St. Cyr, D.Ph. *Jones*	Jason Willeford *Norman*	Greg Adams, D.Ph. *Clinton*	Kyle Whitehead, D.Ph. *Enid*

OKLAHOMA

405-521-3815 • Fax 405-521-3758

State Board of Pharmacy

2920 N Lincoln Blvd Ste A, Oklahoma City, OK 73105

#1-W-5896

Wholesale Distributor

EXPIRES MAY 31, 2025

Mailing Address:

ENDEAVOR DISTRIBUTION LLC
7400 PLAZA MAYOR BLVD STE 200
OKLAHOMA CITY OK 73149

Issued to:

ENDEAVOR DISTRIBUTION LLC
7400 PLAZA MAYOR BLVD STE 200
OKLAHOMA CITY OK 73149

2025

Lic. Fee: $200.00
Receipt No.: 14540987
Date: 5/10/2024

This License is not transferable.

License must be conspicuously displayed in the location to which it is issued.

Bureau of Narcotics and Dangerous Drugs Control
OKLAHOMA

REGISTRANT	REGISTRATION #	ISSUE DATE	EXPIRATION DATE
ENDEAVOR DISTRIBUTION LLC	[redacted]	10/05/2023	10/31/2024

ADDRESS

7400 PLAZA MAYOR BLVD, SUITE 200
OKLAHOMA CITY Oklahoma 73149

SCHEDULES	BUSINESS ACTIVITY/REGISTRATION TYPE
2, 3, 4, 5	Pharmaceutical Distributor

Discipline: None

Donnie Anderson

DONNIE ANDERSON, Director

Section 304 (63 OS 3-304) of the Uniform Controlled Dangerous Substances Act provides that the Director may limit, condition, deny, suspend, or revoke a registration to manufacture, distribute, dispense, prescribe, administer, or use for scientific purposes a controlled dangerous substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, OR BUSINESS ACTIVITY AND IT IS NOT VALID AFTER THE EXPIRATION DATE. CERTIFICATE MUST BE READILY RETRIEVABLE AT ALL TIMES.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	08-31-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	07-11-2023

ENDEAVOR DISTRIBUTION
7400 PLAZA MAYOR BLVD STE 200
OKLAHOMA CITY, OK 731494901

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	08-31-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	07-11-2023

ENDEAVOR DISTRIBUTION
7400 PLAZA MAYOR BLVD STE 200
OKLAHOMA CITY, OK 731494901

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. [redacted]

Application/License No. TBD

Endeavor Distribution, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 7400 Plaza Mayor Boulevard, Suite 200 OKLAHOMA CITY OKLAHOMA 73149 (Address of Applicant/Principal), as PRINCIPAL, and Arch Insurance Company (Surety Company), a corporation organized under the laws of the state of Missouri (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is Harborside 3, 210 Hudson Street, Suite 300, Jersey City NJ 07311 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 06/01/2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 6th day of June, 2024.

APPLICANT/PRINCIPAL
Endeavor Distribution, LLC

Jason Sievers
Authorized Representative

SURETY COMPANY
Arch Insurance Company

Surety Company's Representative

Christopher Kolger, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Aaron Steffey

Witness Konae Mignott

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

AIC 0000348983

Bond SU 7111138-0000

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated. Not valid for Note, Loan, Letter of Credit, Currency Rate, Interest Rate or Residential Value Guarantees.

POWER OF ATTORNEY

Know All Persons By These Presents:
That the Arch Insurance Company, a corporation organized and existing under the laws of the State of Missouri, having its principal administrative office in Jersey City, New Jersey (hereinafter referred to as the "Company") does hereby appoint.

Aaron Steffey and Chris Kolger of Houston, TX (EACH)

its true and lawful Attorney(s)in-Fact, to make, execute, seal, and deliver from the date of issuance of this power for and on its behalf as surety, and as its act and deed Any and all bonds, undertakings, recognizances and other surety obligations, in the penal sum not exceeding One Million Five Hundred Thousand Dollars (1,500,000.00) This authority does not permit the same obligation to be split into two or more bonds in order to bring each such bond within the dollar limit of authority as set forth herein.

The execution of such bonds, undertakings, recognizances and other surety obligations in pursuance of these presents shall be as binding upon the said Company as fully and amply to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal administrative office in Jersey City, New Jersey

This Power of Attorney is executed by authority of resolutions adopted by unanimous consent of the Board of Directors of the Company on December 11, 2020, true and accurate copies of which are hereinafter set forth and are hereby certified to by the undersigned Secretary as being in full force and effect

"VOTED, That the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, or the Secretary shall have the power and authority to appoint agents and attorneys-in-fact, and to authorize them subject to the limitations set forth in their respective powers of attorney, to execute on behalf of the Company, and attach the seal of the Company thereto, bonds, undertakings, recognizances and other surety obligations obligatory in the nature thereof, and any such officers of the Company may appoint agents for acceptance of process."

This Power of Attorney is signed, sealed and certified by facsimile under and by authority of the following resolution adopted by the unanimous consent of the Board of Directors of the Company on December 11, 2020

VOTED, That the signature of the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, and the signature of the Secretary, the seal of the Company, and certifications by the Secretary, may be affixed by facsimile on any power of attorney or bond executed pursuant to the resolution adopted by the Board of Directors on December 11, 2020, and any such power so executed, sealed and certified with respect to any bond or undertaking to which it is attached, shall continue to be valid and binding upon the Company In Testimony Whereof, the Company has caused this instrument to be signed and its corporate seal to be affixed by their authorized officers, this 6th day of August, 2021

Attested and Certified

Regan A. Shulman, Secretary

Arch Insurance Company
CORPORATE SEAL 1971
Missouri

Arch Insurance Company

Stephen C. Ruschak, Executive Vice President

STATE OF PENNSYLVANIA SS
COUNTY OF PHILADELPHIA SS

I, Michele Tripodi, a Notary Public, do hereby certify that Regan A Shulman and Stephen C. Ruschak personally known to me to be the same persons whose names are respectively as Secretary and Executive Vice President of the Arch Insurance Company, a Corporation organized and existing under the laws of the State of Missouri, subscribed to the foregoing instrument, appeared before me this day in person and severally acknowledged that they being thereunto duly authorized signed, sealed with the corporate seal and delivered the said instrument as the free and voluntary act of said corporation and as their own free and voluntary acts for the uses and purposes therein set forth.

Commonwealth of Pennsylvania - Notary Seal
MICHELE TRIPODI, Notary Public
Philadelphia County
My Commission Expires July 31, 2025
Commission Number 1162622

Michele Tripodi, Notary Public
My commission expires 07/31/2025

CERTIFICATION 7

I, Regan A. Shulman , Secretary of the Arch Insurance Company, do hereby certify that the attached Power of Attorney dated August 6, 2021 on behalf of the person(s) as listed above is a true and correct copy and that the same has been in full force and effect since the date thereof and is in full force and effect on the date of this certificate, and I do further certify that the said Stephen C Ruschak, who executed the Power of Attorney as Executive Vice President, was on the date of execution of the attached Power of Attorney the duly elected Executive Vice President of the Arch Insurance Company

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seal of the Arch Insurance Company on this 3rd day of June, 2024.

Regan A. Shulman, Secretary

This Power of Attorney limits the acts of those named therein to the bonds and undertakings specifically named therein and they have no authority to bind the Company except in the manner and to the extent herein stated.

PLEASE SEND ALL CLAIM INQUIRIES RELATING TO THIS BOND TO THE FOLLOWING ADDRESS:
Arch Insurance – Surety Division
3 Parkway, Suite 1500
Philadelphia, PA 19102

To verify the authenticity of this Power of Attorney, please contact Arch Insurance Company at Surety.Authentic@archinsurance.com Please refer to the above named Attorney-in-Fact and the details of the bond to which the power is attached.

Arch Insurance Company
CORPORATE SEAL 1971
Missouri

Oklahoma State Board of
PHARMACY

Last Updated: 6/25/2024 5:19:45 AM

Technician Detail

Back

Name	KARLO CAEZAR VALERIO
Type	Technician
Number	[redacted]
City	OKLAHOMA CITY, OK 73107
Status	License in Good Standing
Issue Date	05/30/2018
Renewed Date	02/13/2024
Expire Date	03/31/2025
End Date	
Immunization?	No

Disciplinary Action

Click on any of the Underlined headings to sort by that column.

Case Date **Case Number**

No Disciplinary Action

< Prev Next >

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Endeavor Distribution LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 7400 Plaza Mayor Blvd, Ste 200

City Oklahoma City State OK Zip 73149

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (405) 839-7891 Website _____

Licensing Company Email support@endeavordistribution.com

Section 2: Personal Information

First Karlo Middle Caezar Last Valerio

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] 25th St.

City Oklahoma City State OK Zip 73107

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The University of Oklahoma		08/11-05/18	
Address	City	State	Zip
660 Parrington Oval	Norman	OK	73019
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Classen School of Advanced Studies		08/07-05/11	
Address	City	State	Zip
1901 N Ellison Ave	Oklahoma City	OK	73106
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/93-Present	[redacted]25th St.	Oklahoma City	OK	73107
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Endeavor Distribution LLC			04/24-Present
Business Address	**City**	**State**	**Zip**
7400 Plaza Mayor Blvd, Ste 200	Oklahoma City	OK	73149
Phone	**Title**	**Number of Employed Hours**	
(405) 839-7891	Designated Representative	184	

Description of Duties

- Cross examine perpetual inventory with utilization to ensure supply on-hand is properly stocked.
- Ensure two-person check-in validation of controlled substances in narcotics room.

Business Name			From - To (MM/YY – MM/YY)
Pharmacorr LLC			02/13-04/24
Business Address	**City**	**State**	**Zip**
7400 Plaza Mayor Blvd, Ste 100	Oklahoma City	OK	73149
Phone	**Title**	**Number of Employed Hours**	
(888) 321-7774	Pharmacy Technician	23,280	

Description of Duties

- Examine patient profiles to view fill history of prescriptions to check if refill too soon.
- Keep controlled substances logbook up-to-date with perpetual inventory.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Karlo Caezar Valerio, **certify that as the designated representative for**

Endeavor Distribution LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KCV I am at least 21 years of age;
3. KCV I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KCV I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KCV I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KCV I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KCV I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Karlo Valerio

Print Name (First, Last)

KCValerio

Original Signature (electronic, copies or stamps not accepted)

6/17/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Karlo Valerio

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/17/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Oklahoma, ss. County of Oklahoma

I, Karlo Valerio, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/17/2024

Date

Subscribed and Sworn to before me this 17th day of June 2024.

Jacqueline N. Konarik

Notary Public Signature

JACQUELINE N. KONARIK NOTARY # 06009396 EXP. 09/25/26 PUBLIC STATE OF OKLAHOMA (Seal)

ENDEAVOR DISTRIBUTION

Current Employees for Endeavor Distribution:

Karlo Valerio – Designated Representative/Pharmacy Technician

Deborah Rickard – Facility Manager

ENDEAVOR DISTRIBUTION LLC
7400 PLAZA MAYOR BOULEVARD, SUITE 200 OKLAHOMA CITY, OKLAHOMA 73149
(888)321-7774 EXT.1405

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Clean Earth of Alabama, Inc.

Physical Address: 402 Webster Chapel Road

City: Glencoe State: AL Zip: 35905

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 256-666-4331 Website: https://www.cleanearthinc.com/

Name of Designated Representative (DR): Bradley Phillips

Licensing Company Email: dhill@cleanearthinc.com DR Email: bphillips1@cleanearthinc.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	■ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A accept for destruction only

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Clean Earth LLC

Corporation/Organization Name: Clean Earth of Alabama, Inc.

Mailing Address: 402 Webster Chapel Road

City: Glencoe State: AL Zip: 35905

Telephone: 256-666-4331 Email: bphillips1@cleanearthinc.com

Contact Person Name: Bradley Phillips

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Clean Earth of Alabama, Inc.

Facility Name

Sarah Kowalczyk

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/27/24

Date

Board Use Only	Date Received: 5/9/24	Amount: $1000 - check 1000001546

CleanEarth.

List of Officers

Name	Title
Jeffrey Andrew Beswick	President
Jeffrey Alfred Diaz	Vice President, Treasurer
Sarah Papineau Kowalczyk	Secretary

Fingerprints completed 12/4/23 under 21st Century Environmental

CleanEarth.

Clean Earth of Alabama, Inc. Ownership

Clean Earth LLC 100% ownership

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CLEAN EARTH OF ALABAMA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-NINTH DAY OF JANUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CLEAN EARTH OF ALABAMA, INC." WAS INCORPORATED ON THE TWENTY-FIFTH DAY OF APRIL, A.D. 2016.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





6025151 8300

SR# 20240274732

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202689206

Date: 01-29-24

Wes Allen
Secretary of State

P.O. Box 5616
Montgomery, AL 36103-5616

STATE OF ALABAMA

I, Wes Allen, Secretary of State of Alabama, having custody of the Great and Principal Seal of said State, do hereby certify that

the entity records on file in this office disclose that Clean Earth of Alabama, Inc. a Delaware entity, qualified in the State of Alabama on June 2, 2016. The Alabama Entity Identification number for this entity is 000-363-740. I further certify that the records do not disclose that said qualification has been revoked, cancelled or terminated.

In Testimony Whereof, I have hereunto set my hand and affixed the Great Seal of the State, at the Capitol, in the city of Montgomery, on this day.

01/02/2024

Date

Wes Allen **Secretary of State**

20240102000006746

Alabama State Board of Pharmacy

2024

This is to certify:

CLEAN EARTH OF ALABAMA, INC.
402 WEBSTER CHAPEL ROAD
GLENCOE, AL 35905

Permit Number:

196530

Is Duly Licensed as a:

Wholesale Drug Distributor (Reverse Distribu

Specialty Services:

Designated Representative

BRADLEY KREEG PHILLIPS

DR0004

IN COMFORMITY WITH THE PROVISIONS OF ACT #205, GENERAL ACTS OF ALABAMA, 1966 SPECIAL SESSION, AND RULES AND REGULATIONS OF THE BOARD. THIS CERTIFICATE MUST BE CONSPICIOUSLY DISPLAYED AND EXPIRE ON THE LAST DAY OF

December 2024

THIS IS YOUR RECEIPT FOR FEE PAID AS REQUIRED BY LAW
THIS PERMIT IS NOT TRANSFERRABLE

Donna C Yeatman
EXECUTIVE SECRETARY

Alabama State Board of Pharmacy

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE

2024

Controlled Substance Number:

196530

Business Activity:

VOID

Schedules:

VOID

The Controlled Substance Act of 1971 reads in part as follows:
Section 304 (Revocation and Suspension of the Registration.)

(a) A registration under Section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Certifying Boards upon a finding that the registrant:

(1) Has furnished false or fraudulent material information in any application filed under this Act,

(2) Has been convicted of a felony under any State or Federal law relating to any controlled substance or

(3) Has had his Federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances

(4) Has violated the provisions Act 205 (al-a32) Code of Alabama 1940 (Recomp. 1958)

Date Issued: VOID

Expiration Date: VOID

VOID

CERTIFICATE MUST BE PROMINENTLY DISPLAYED AT ALL TIMES

THIS REGISTRATION IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K09680664

Application/License No. TBD

Clean Earth of Alabama, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 402 Webster Chapel Road Glencoe, AL 35905 (Address of Applicant/Principal), as PRINCIPAL, and Federal Insurance Company (Surety Company), a corporation organized under the laws of the state of Indiana (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 202B Hall's Mill Road, Whitehouse Station, NJ 08889 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 21, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of November, 2023.

APPLICANT/PRINCIPAL

COMPANY
Clean Earth of Alabama, Inc.

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY

Federal Insurance Company

Surety Company's Representative

Kristen D. Pedrick, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Haley Striewig, Witness

Witness Patricia C. Robinson, Witness

Countersigned by:

N/A
Nevada Resident Agent

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Wisconsin corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Kristen D. Pedrick and Robert N. Striewig Jr. of Mechanicsburg, Pennsylvania ----------

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **15th** day of **January, 2020.**

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

Steven M Haney

Stephen M. Haney, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **15th** day of **January, 2020** before me, a Notary Public of New Jersey, personally came Dawn M. Chloros and Stephen M. Haney, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Dawn M. Chloros and Stephen M. Haney, being by me duly sworn, severally and each for herself and himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

KATHERINE J. ADELAAR
NOTARY PUBLIC OF NEW JERSEY
No. 2316685
Commission Expires July 16, 2024

Katherine J. Adelaar
Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Dawn M. Chloros, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this November 21, 2023

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Clean Earth of Alabama, Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 402 Webster Chapel Road

City: Glencoe State: AL Zip: 35905

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (800) 739-9156 Website: https://www.cleanearthinc.com/

Licensing Company Email: bphillips1@cleanearthinc.com

Section 2: Personal Information

First: Bradley Middle: Kreeg Last: Phillips

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Julia Drive

City: Glencoe State: AL Zip: 35905

Telephone: [redacted] Email: bphillips1@cleanearthinc.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Glencoe High School		09/86 - 06/90	
Address	**City**	**State**	**Zip**
803 Lonesome Bend Rd	Glencoe	AL	35905
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/13 - Present	[redacted] Julia Drive	Glencoe	AL	35905
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Clean Earth of Alabama, Inc.			07/20 - Present	
Business Address		**City**	**State**	**Zip**
402 Webster Chapel Road		Glencoe	AL	35905
Phone	**Title**		**Number of Employed Hours**	
(800) 739-9156	General Manager		7,680+	
Description of Duties				
Responsible for facility P&L; Provide support for customer service, sales, material management and plant operations; Ensure that the plant is compliant; Ensure that all waste processing functions are complete				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Bradley Mullen
Original Signature (electronic, copies or stamps not accepted)

4-9-2024
Date

I, Bradley Phillips, **certify that as the designated representative for**

Clean Earth of Alabama, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BP ✓ I am at least 21 years of age;
3. BP ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BP ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BP ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BP ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BP ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Bradley Phillips

Print Name (First, Last)

Bradley Phillips

Original Signature (electronic, copies or stamps not accepted)

4-9-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bradley Phillips

Print Name (First, Last)

Bradley Phillips

Original Signature (electronic, copies or stamps not accepted)

4-9-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of Etowah

I, Bradley Phillips, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Bradley Phillips

Original Signature

4-9-2024

Date

Subscribed and Sworn to before me this 9th day of April.

Brooke Bell NP

Notary Public Signature

(Seal)

Name

Clean Earth of Alabama, Inc.

Adkison, Kelley
Bailey, Amanda
Bailey, Sammy J
Barker, Jasper C
Bateman, Glim
Battles, Derrick E
Bean, Benjamin D
Black, John R
Blackwell, Kendrick D
Borders, Jakobe
Brooks, Jordan
Bryant, Chad W
Bush, Elijah T
Caywood, Erica R
Collier, Brent L
Dudley, Candie L
Duncan, Barrious T
Foster, Justin A
Franklin, Coleby J
Gray, Amante T
Griffith, David W
Hairrell, Nicholas R
Heino, Calvin L
Helms, Dana L
Hogg, Fargas
Holliday, Elmus A
Hollis, Kenneth W
Hooks, Tracy A
Hulsey, Christopher H
Hunter, Christina E
Jacobs, Joshua G
Johnson, Don L
Johnson, Randall D
Jones, Brandon S
Jones, Bryan C
Jones, Kevin G
Kenney, Allen
Kuykendall, Christopher N
Lawson, Milton
Lee, Charles
Lee, Justin N
Lewis, Kaleb M
Lewis, Kelly R

Little, Donald M	
Lusk, Sumer D	
Mahone, Darian	
Medley, Jana D	
Minton, Chasity	
Moats, Allen E	
Moon, Kaleb E	
Morgan, Randall	
Mostella, Camila D	
Myers, Cardavion L	
Myers, Carl	
Ortiz, Luis M	
Pate, Genevieve R	
Patton, Robert D	
Phillips, Bradley	
Pitts, Reginald W	
Powell, Jason W	
Powell, Seth	
Presley, Robert	
Pritchett, Adam R	
Ragland, Brian	
Ransaw, Derrick L	
Ransaw, Torrey A	
Smith, Marvin	
Sorrell, Suzy	
Steele Dubose, N'Kosi	
Steele, Maya	
Strickland, Robert A	
Swain, Prince C	
Tadder, Patricia A	
Thornton, Orlando J	
Tillison, Gavin A	
Walden, Christopher D	
Westbrook, Virgil	
Wetzel, Nathan P	
Wilson, James C	
Wilson, Michael L	
Winston, Aaron	
Woods, Javien K	
Worthing, Emily E	in office 1 week a month
David Dunlap	starting 05-20-2024
Houston Hughes	starting 05-20-2024

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Y

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Exel Inc. dba DHL Supply Chain (USA)

Physical Address: 1141 E. Harrisburg Pike

City: Middletown State: PA Zip: 17057

Mailing Address (if different from physical address): 360 Westar Blvd, Dept 555

City: Westerville State: OH Zip: 43082

Telephone: 717-574-5644 Website: www.exel.com

Name of Designated Representative (DR): Scott Hile

Licensing Company Email: DHL@IQVIA.com DR Email: scott.hile@dhl.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others: OTC Drugs, OTC Devices	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Third Party Logistics Provider

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

See Attached

Mark A. Lucich

→ Original Signature (electronic, copies or stamps not accepted)

11/28/23

→ Date

DHL Supply Chain
Regulatory Affairs

360 Westar Boulevard, Westerville, OH 43082

May 3, 2023

To whom it may concern,

Exel Inc. d/b/a DHL Supply Chain (USA) ("DHL") is submitting this letter in reference to the question on the application regarding pending complaint, investigation, or disciplinary actions.

Exel Inc. d/b/a DHL Supply Chain (USA) ("DHL") is a part of Deutsche Post DHL Group, the world's leading contract logistics provider, and has tens of thousands of employees across North America. At any given time, DHL is a named defendant in civil matters, including employment cases. Based on knowledge and belief of the respondent completing this application after reasonable inquiry, DHL is not involved in any pending criminal proceedings. Nor is DHL part of any pending malpractice claims, civil claims, or lawsuits in connection with drugs/devices.

Attached is a letter from the State Board for the following item:

On April 23, 2023, DHL received a notice from the California State Board of Pharmacy indicating that the Board issued a fine against DHL for its failure to notify the Board of a change in its Designated Representative for the site located at 5920 Corporate Drive, St. Joseph, MO 64507. Please note that the issuance of a fine by the Board is not considered a disciplinary action or reportable and the fine was paid for in full within the allotted time.

Please be assured that DHL takes these matters very seriously and has implemented corrective actions to prevent similar issues from occurring in the future. If you have any concerns regarding the matters set forth in this notice, please do not hesitate to contact DHL Regulatory Affairs at regulatory@dhl.com.

Respectfully,

John Kropczynski, BSE, MBA

John Kropczynski

Director, Regulatory Affairs, America's

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

April 12, 2023

DATED MATERIAL ENCLOSED

EXEL INC_DBA DHL SUPPLY CHAIN (USA)
ATTN: KENNETH SUREDDIN, CEO
5920 CORPORATE DRIVE
ST JOSEPH, MO 64507

RE: CI 2022 99663
EXEL INC_DBA DHL SUPPLY CHAIN (USA)
NPL 1001

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- May 12, 2023: Unless the Citation is contested payment of fine(s) must be received by the Board.
- April 26, 2023: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- May 12, 2023: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By:

Suelynn Yee
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **May 12, 2023.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than April 26, 2023 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than May 12, 2023 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2022 99663	EXEL INC_DBA DHL SUPPLY CHAIN (USA), NPL 1001

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4160 subd. (g)	A third-party logistics provider shall notify the board in writing, on a form designated by the board, within 30 days of the date when a responsible manager ceases to act as the responsible manager, and shall on the same form propose another designated represenative-3PL to take over and the responsible manager.	$5,000.00

CONDUCT:

Business and Professions Code section 4160(g) requires a third-party logistics provider to notify the Board in writing, on a form designed by the Board, within 30 days of the date when a responsible manager ceases to act as the responsible manager and shall on the same form propose another designated representative-3PL to take over as the responsible manager. Specifically, on February 3, 2023, the Board received an Application for Change of Responsible Manger from Exel INC DBA DHL Supply Chain (USA), which had been signed under penalty of perjury by a corporate officer and the newly designated responsible manager-in-charge (RMG). The form indicated that the prior RMG, Donald Kragel (DRL 40449), dissociated on June 30, 2021 and that Ryan Stocking (DRL 40676) was designated as the new RMG the following day. Exel INC DBA DHL Supply Chain (USA) failed to notify the Board of their dissociated RMG for 583 days (June 30, 2021 – February 3, 2023). Similarly, Exel INC DBA DHL Supply Chain (USA) failed to notify the Board of their new RMG for 582 days (July 1, 2021 – February 3, 2023).

CITATION ISSUED ON: April 12, 2023 | TOTAL AMOUNT OF FINE(S): $5,000.00

PAYMENT OF FINE(S) DUE BY: May 12, 2023

UPS CampusShip: View/Print Label

1. **Ensure there are no other shipping or tracking labels attached to your package.** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.

2. **Fold the printed label at the solid line below.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.

3. **GETTING YOUR SHIPMENT TO UPS**
   Customers with a Daily Pickup
   Your driver will pickup your shipment(s) as usual.

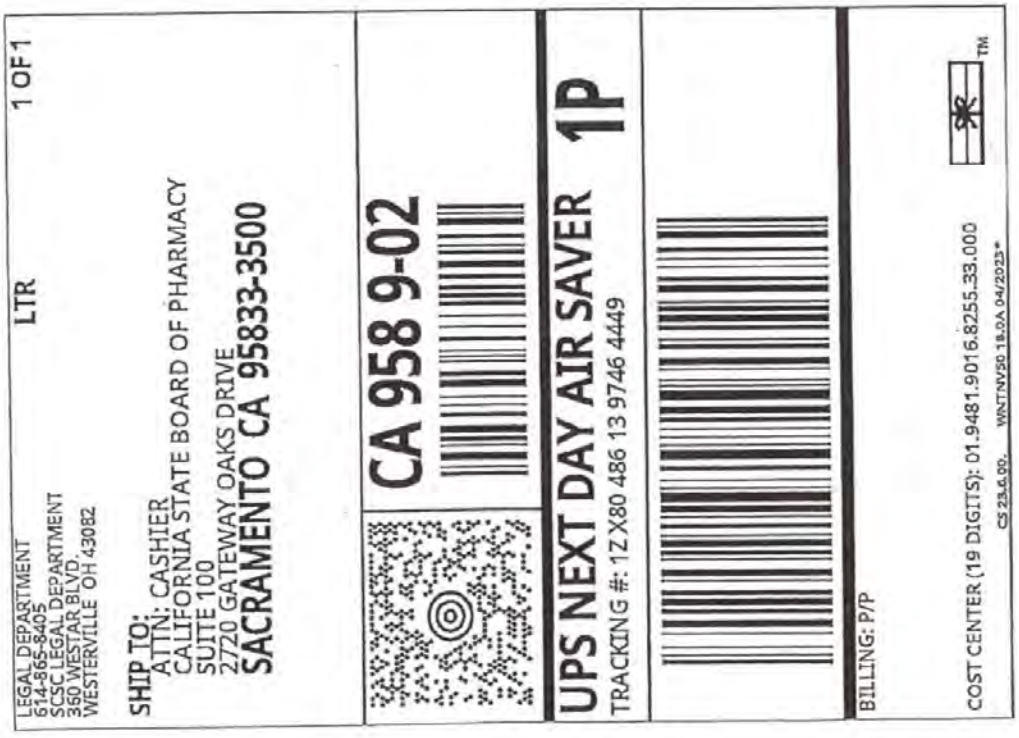
   Customers without a Daily Pickup
   Take your package to any location of The UPS Store®, UPS Access Point(TM) location, UPS Drop Box, UPS Customer Center, Staples® or Authorized Shipping Outlet near you. Items sent via UPS Return Services(SM) (including via Ground) are also accepted at Drop Boxes. To find the location nearest you, please visit the Resources area of CampusShip and select UPS Locations.
   Schedule a same day or future day Pickup to have a UPS driver pickup all your CampusShip packages.
   Hand the package to any UPS driver in your area..

UPS Access Point™
THE UPS STORE
752 N STATE ST
WESTERVILLE ,OH 43082

UPS Access Point™
CVS STORE # 6155
145 S STATE ST
WESTERVILLE ,OH 43081

UPS Access Point™
THE UPS STORE
1491 POLARIS PKWY
COLUMBUS ,OH 43240

FOLD HERE



DHL Supply Chain



Legal Department
360 Westar Boulevard
Westerville, Ohio 43082

May 3, 2023 via UPS

California State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

RE: Exel dba DHL Supply Chain – CI 2022 99663
Settlement - $5,000.00

To whom it may concern:

Enclosed please find the following settlement payments:

- a check payable to California State Board of Pharmacy in the amount of $5,000.00.

Please contact the undersigned if you have any questions.

Yours sincerely,

Michal Armstrong
Senior Legal Operations Analyst
Legal Services - Americas
Legal-Services@dhl.com
614.865.8415

Enclosures

CC: Lori Hill
Elaine Darr
John Kropczynski

DHL Supply Chain – Excellence. Simply delivered.

DHL Supply Chain
Regulatory Affairs

360 Westar Boulevard, Westerville, OH 43082

October 14, 2022

RE: NV Initial Wholesaler Application

To whom it may concern,

Exel Inc. d/b/a DHL Supply Chain (USA) ("DHL") is submitting this letter in reference to the question on Wholesaler Application regarding pending complaint, investigation, or disciplinary actions.

[Exel Inc. d/b/a DHL Supply Chain (USA) ("DHL") is a part of Deutsche Post DHL Group, the world's leading contract logistics provider, and has tens of thousands of employees across North America. At any given time, DHL is a named defendant in civil matters, including employment cases. Based on knowledge and belief of the respondent completing this application after reasonable inquiry, DHL is not involved in any pending criminal proceedings. Nor is DHL part of any pending malpractice claims, civil claims, or lawsuits in connection with drugs/devices.]

Attached are letters from the State Board for the following 2 items:

1. On March 27, 2019, DHL received a notice from the Colorado Board of Pharmacy indicating that the Board initiated disciplinary action against DHL in connection with DHL's failure to notify the Board of a change in its Designated Representative for the site located at 1635 Stone Ridge Drive, Stone Mountain, GA 30083-118. The matter was resolved with the Board as of April 29, 2019 and is now closed.

2. On August 10, 2022, DHL received a proposed Imposition of Civil Fine from the Board in connection with DHL's alleged failure to timely notify the Board of a change in its Designated Representative. DHL accepted the Imposition of Civil Fine in the amount of $500, which was a technical violation only and not related to the delivery of patient care. Although we did notify on time and at all times a DR was present at the facility, the method of notification was technically incorrect which led to the delay. The matter was resolved with the Board as of September 19, 2022.

Please be assured that DHL takes these matters very seriously and has implemented corrective actions to prevent similar issues from occurring in the future. If you have any concerns regarding the matters set forth in this notice, please do not hesitate to contact DHL Regulatory Affairs at regulatory@dhl.com.

Respectfully,

John Kropczynski, BSE, MBA

John Kropczynski

Director, Regulatory Affairs, America's

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2022-000354

I, JONATHAN MENEZES, as an agent for Exel Inc. Dba DHL Supply Chain (USA), admit and agree the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of Third-Party Logistics Provider License No. 156932, and over this Imposition of Civil Fine.

1. On June 30, 2021, we appointed a new Facility Manager. On March 21, 2022, the Board received our Change of Facility Manager form with the new Facility Manager notification; 264 days after the Facility Manager change occurred. **This is a violation of 12 AAC 52.697(c).**

We admit that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of my license pursuant to AS 08.01.75 and 12 AAC 52.697(c). We are agreeing to this Imposition of a Civil Fine of five hundred dollars ($500) in cash, certified check, or money order payable to the **"State of Alaska"** within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

We have the right to consult with an attorney, and a right to an administrative hearing on the facts in this case. We understand and agree by voluntarily signing this Imposition of Civil Fine, we are waiving our rights to counsel and to a hearing on this matter.

JONATHAN MENEZES
Name/Title, Respondent
SENIOR DIRECTOR

9/19/22
Date

SUBSCRIBED AND SWORN TO before me this 19th day of September, 2022, at Delaware County, Ohio, ~~Alaska~~.

SEAL

Allison E. Haedt
Notary Public ~~in and for Alaska~~

CLP
EP

Allison E. Haedt
Notary Printed Name
My commission expires: N/A

NOTARIAL SEAL
STATE OF OHIO

Allison Haedt, Attorney At Law
NOTARY PUBLIC - STATE OF OHIO
My commission has no expiration date
Sec. 147.03 R.C.

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

FORM REVISED 5/01/2015

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

In the Matter of:)
)
Exel Inc.)
Dba DHL Supply Chain (USA))
)
Respondent)
Case No. 2022-000354

ORDER

The Alaska Board of Pharmacy (Board), having examined the Imposition of Civil Fine, Case No. 2022-000354, regarding license number 156932, for failure to timely notify the Board of a Facility Manager change, hereby adopts the Imposition of Civil Fine.

The Board has determined this is a technical violation of professional licensing statutes and regulations, therefore this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 22nd day of September, 2022, at Anchorage, Alaska.

ALASKA BOARD OF PHARMACY

By: Justin Ruffridge
Board Chair

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

DHL Supply Chain

570 Polaris Parkway
Westerville, OH 43082

April 30, 2019

RE: Exel Inc. d/b/a DHL Supply Chain (USA) ("DHL") – Notice of Colorado State Board of Pharmacy Discipline Action

To whom it may concern,

On March 27, 2019, DHL received a notice from the Colorado State Board of Pharmacy (the "Board") indicating that the Board initiated disciplinary action against DHL in connection with DHL's failure to timely notify the Board of a change in its designated representative for the site located at 1635 Stone Ridge Drive, Stone Mountain, GA 30083-118. The matter was resolved with the Board as of April 29, 2019 and is now closed.

Please be assured that DHL takes these matters very seriously and has implemented corrective actions to prevent similar issues from occurring in the future. If you have any questions or concerns regarding the matters set forth in this notice please do not hesitate to contact DHL Regulatory Affairs at Regulatory@dhl.com.

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2019-844

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF EXEL INC., DBA DHL SUPPLY CHAIN (USA), REGISTRATION NO. WHO 8288,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Exel Inc., dba DHL Supply Chain (USA)("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2019-844, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an out-of-state prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2018).

2. Respondent Outlet was originally registered in the State of Colorado on or about November 19, 2010, being issued registration #WHO 8288, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 1635 Stone Ridge Drive, Stone Mountain, Georgia.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit to the Board an application detailing a change in designated representative and fee. In this case, 320 days transpired between March 9, 2018, the date the previous designated representative ceased the position, and January 23, 2019, the date the application and fee were received.

6. On or about February 4, 2019, the Board initiated a complaint against Respondent Outlet because of the delay of 320 days in submitting an application detailing a change in designated representative and fee.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board.

12-42.5-303. Wholesaler license requirements.

(3)(a) An applicant for a wholesaler license shall provide to the board the following information, and any other information deemed appropriate by the board on a form provided by the board:

(I) The name, full business address, and telephone number of the applicant;

(II) The trade and business names used by the applicant;

(III) The addresses, telephone numbers, and names of the contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs;

(IV) The type of ownership or operation of the applicant;

(V) The names of the owner and the operator of the applicant, including:
(A) The name of each partner if the applicant is a partnership;
(B) The name and title of each officer and director, the name of the corporation, and the state of incorporation, if the applicant is a corporation;
(C) The name of the limited liability company, if the applicant is a limited liability company, and the name of the parent company, if any, and the state of incorporation or formation of both; or

(D) The name of the sole proprietor and the business entity if the applicant is a sole proprietorship;

(VI) A list of the licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs; and

(VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board, including but not limited to the information in subsection (5) of this section.

(b) A licensee shall complete and return a form approved by the board at each renewal period. The board may suspend or revoke the license of a wholesaler if the board determines that the wholesaler no longer qualifies for a license.

* * *

Pharmacy Board Rules and Regulations

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to section 12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to section24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of **One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00)**. The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board.

9. **Compliance.** Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to sections 12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under section 12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension

or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability**. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record**. Upon execution by all parties, this Stipulation and Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Effective Date**. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

Mark A. Lemaire Dated: 4/18/19

Authorized Representative

Vice President, General Counsel and Secretary

Name / Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 29 day of April, 2019.

State Board of Pharmacy

BY: _____
Dmitry Kunin
Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 29th day of April 2019, addressed as follows:

By electronic mail:

Exel Inc. dba DHL Supply Chain USA
1635 Stone Ridge Dr
Stone Mountain, GA 30083-1118

Email: renewals@licenselogix.com; and andrew.post@dhl.com

Linda Stanko
Agent of the Board

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

February 04, 2019

Exel Inc. dba DHL Supply Chain (USA)
Attn: Designated Representative
1635 Stone Ridge Dr
Stone Mountain, GA 30083-1118

Also sent via email: renewals@licenselogix.com

RE: Case 2019-844

Dear Designated Representative:

The Colorado State Board of Pharmacy ("Board") has received the attached complaint regarding the conduct of the Board-registered out-of-state prescription drug wholesaler detailed above. The Board is investigating this complaint. It is being sent to you as the designated representative of the above listed out-of-state prescription drug wholesaler. The first step in the process is to obtain your response to the allegations raised in the complaint. At this point, no assumption has been made about the truth or validity of any information provided to the Board.

Please send a written response within thirty (30) days of the date of this letter as indicated above. An earlier response may expedite the Board's review of this matter. To facilitate an efficient and timely review, please type your response. If this is not possible, please legibly print your response.

We encourage you to respond electronically. If you do, please submit the response to dora_pharmacyboard@state.co.us. Please scan and attach any relevant documents. Address all correspondence to the Board.

Also, please be sure that any copies submitted with your response are legible. Be sure to include the case number listed above on all correspondences and address your response to my attention.

It is the policy of the Division of Professions and Occupations to copy your attorney (if you are represented) on all correspondences in order to assure that your attorney is aware of the developments in your case. If you are represented by an attorney in this matter, please provide the Board in writing with your attorney's contact information. If the Board already has your attorney's contact information, your attorney name

should be identified below as a carbon copy of "cc," indicating that a copy of this letter was sent to that attorney. If at any time it appears that the Board does not have the correct information regarding your legal representation, please update the Board and provide your attorney with a copy of all correspondences from the Board.

We strongly encourage you to begin preparing your response to the complaint as soon as possible, as extensions to the thirty day response time will not be granted except in very limited circumstances. Additionally, if you choose to be represented by an attorney, please contact him or her immediately. A delay in doing so will not be grounds for an extension.

Following receipt of your response, the Board will review the complaint and your response thereto. The Board will then determine what further action, if any, is warranted. Please note you will be advised in writing of the Board's disposition of this complaint.

Thank you for your cooperation and prompt attention to this matter. If you have any questions, please contact me at dora_pharmacyboard@state.co.us or (303) 894-7800.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Lana Hyatte
Program Specialist

Enclosures: Q&A Brochure
Complaint

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

Management Branch
Office of Enforcement - Pharmacy Inspections

MEMORANDUM			
Board/Program:	State Board of Pharmacy	**Specialist:**	Lana Hyatte
Case Number:	2019-844	**Date of Memorandum:**	02/01/2019

RESPONDENT INFORMATION			
Name:	Exel Inc. dba DHL Supply Chain (USA)		
License Type:	WHO	**Number:**	8288

SUMMARY

On 01/23/19, the Colorado State Board of Pharmacy ("Board") received an application from Exel Inc. dba DHL Supply Chain (USA), detailing a change of designated representative along with fee (**Attachment 1**). This application indicates that on 03/09/18, Thomas Flynn ceased being the designated representative. Consequently, **320 days** elapsed between the 03/09/18 date that Mr. Flynn ceased being the designated representative and the 01/23/19 date the application and fee were received.

Board Rule 15.01.14 (c) states that within thirty calendar days any changes in information shall be submitted to the Board. Within the thirty days after termination of the former designated representative's employment, an application to transfer the registration to the new representative and paid transfer fee must be submitted. CRS 12-42.5-123(1)(c)(I)(II)(III) provides that the Board may suspend, revoke, refuse to renew, or otherwise discipline any registration issued by it, after a hearing, upon proof that the registrant has violated any lawful rules of the Board or any state or federal laws pertaining to drugs.

Accordingly, per standard procedure, please initiate a complaint against the registration of this Wholesaler Out-of-State drug outlet using this memo and a copy of the 01/23/19 application.

ATTACHMENTS	EXHIBITS
1. Application	1.

Reviewer's Initials

PAID
35.00 mo
1607875

DPO 920
JHN23F19/002492

Division of Professions and Occupations
Office of Licensing—Pharmacy
1560 Broadway, Suite 1350
Denver, CO 80202
(303) 894-7800 / Fax (303) 894-7693
www.dora.colorado.gov/professions

Application for Registration OUT-OF-STATE WHOLESALER / DISTRIBUTOR OF PRESCRIPTION DRUGS and/or CONTROLLED SUBSTANCES

New Registration or Ownership Transfer: **$450**
Change Location: **$125**
Change Name or Change Designated Representative: **$35**
Fees may be paid by a check or money order drawn in U.S. dollars on a U.S. bank and made payable to State of Colorado

The content of this application must not be changed. If the content is changed, the applicant may be referred to the Colorado State Attorney General's Office for violation of Colorado law.

If additional pages are attached to respond to requested information in any part of the application, please indicate the number of the item to which you are responding.

PART 1.

Select from the following and submit the appropriate fee for each selection:

☐ **I am submitting an application for NEW Out-of-State Wholesaler registration.** $450
- *Enclose fee with your application and continue to Part 2.*

—OR—

☐ **I am reporting a TRANSFER OF OWNERSHIP for a current registration.** $450
Previous owner name: _____
Effective date of new ownership: _____

☒ **I am reporting a change in existing registration as follows:** (select all that apply)

☐ **CHANGE OF LOCATION** $125
Previous location: _____
Effective date of relocation: _____

☐ **CHANGE OF BUSINESS NAME** $35
Colorado registration number: _____
Previous business name: _____
New business name: _____
Effective date of new name: _____

☒ **CHANGE OF DESIGNATED REPRESENTATIVE** $35
Colorado registration number: WHO.0008288
New Designated Representative Name: James Patrick Kennedy
New Designated Representative Social Security No: 259-49-9617
Previous Designated Representative Name: Thomas Flynn
Effective date of change: 3/9/2018
Designated Representative Affidavit (page 5): _____

Total Fee: $ 35

PART 2.

1. Colorado Registration Number: WHO.0008288 *If this is a new registration, leave blank.*
2. Business Name: _____
   List all trade names or DBA names used by business: _____
3. Wholesaler business license number in the state of residence: _____

DESIGNATED REPRESENTATIVE AFFIDAVIT

Facility Name: Exel Inc. dba DHL Supply Chain (USA)

Address: 1635 Stone Ridge Drive, Stone Mountain, GA 30083

I, James Patrick Kennedy, certify the following:

1. I am the designated representative for the above-referenced facility.
2. The information contained in the application and this document is correct including, but not limited to, the responses to the Background Questions in Part 3.
3. I am familiar with the requirements of the Federal Food, Drug and Cosmetic Act and its supporting regulations.
4. I am at least twenty-one years of age.
5. I have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the record keeping related to prescription drugs.
6. I am employed by the applicant or facility in a full-time managerial position.
7. I am actively involved in and aware of the actual daily operation of the wholesaler.
8. I am physically present at the facility during regular business hours, except when the absence of the designated representative is authorized, including but not limited to, sick leave and vacation leave.
9. I do not serve as the designated representative for more than one wholesaler.
10. I do not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or a controlled substance.
11. I do not have any felony, civil, or misdemeanor convictions pursuant to federal, state, or local law. (This includes deferred judgments or deferred sentences.)
12. I agree to notify the Board in writing when I cease to be the designated representative of this facility.
13. I certify that the applicant wholesaler will not distribute any new drug into Colorado not authorized to move into interstate commerce under appropriate federal law.
14. I attest that, pursuant to § 12-42.5-304, C.R.S., I have submitted my fingerprints to the Colorado Bureau of Investigation (CBI) for the purpose of conducting a state and national fingerprint-based criminal history record check utilizing records of the CBI and the Federal Bureau of Investigation (FBI). The Board, which makes the determination of suitability for licensing, will provide the applicant the opportunity to complete, or challenge the accuracy of, the information contained in the FBI identification record. Procedures for obtaining a change, correction, or updating of an FBI identification record are set forth in Title 28, C.F.R. 16.34. The Board will not deny the license based on information in the record until the applicant has been afforded a reasonable time to correct or complete the record, or has declined to do so. Direct all challenges to your record to the FBI's Criminal Justice Information Services Division, Attention: Correspondence Group, 1000 Custer Hollow Rd., Clarksburg, WV 26306.

Per § 12-4-104(13)(a), C.R.S., any applicant who, under oath, supplies false information to an agency in an application for a license, commits perjury in the second degree as defined in § 18-8-503, C.R.S.. In accordance with §§ 18-8-503 and C.R.S. 18-8-501(2)(a)(I), C.R.S., false statements made herein are punishable by law.

Signature: J P K Date: 1-7-19

If the wholesaler is changing designated representatives, indicate the name of the previous designated representative and the date this individual ceased to be the designated representative for this wholesaler.

Previous Designated Representative: Thomas Flynn

Date Ceased to be Designated Representative: 3/9/2018

James Patrick Kennedy

Peachtree Corners, Georgia 30092
(678) 247-3788
kennedypatrick4@gmail.com

SUMMARY

A meticulous and highly reliable supply chain professional with extensive experience in inventory management, international logistics, regulatory compliance, process improvement, metrics and analysis, team development and mentoring, safety control, warehousing, vendor and governmental relations, and SAP training. Excels at finding new ways to streamline efforts and collaborate more effectively as a means of lowering costs and increasing overall accuracy. A driven producer who provides the proper logistics and internal support a company requires to achieve key business objectives.

EXPERIENCE

January 2018-Present

Field Quality Assurance Specialist

- Conduct internal audits and lead communication with government officials in regulatory audits
- Export controlled drugs including preparing documentation and Drug Enforcement Administration expert permit submission
- Review and revise standard operating procedures
- Train new and existing employees on Standard Operating Procedures and Work Instructions
- Provide guidance on regulatory compliance with FDA and DEA regulations

January 2017-October 2017 Hospira, a Pfizer company, Stone Mountain, Georgia

Warehouse Manager

- Provided leadership and motivation during company transition
- Analyzed metrics resulting in improvement of accuracy and productivity
- Counseled employees on errors and perform reviews
- Chaired the distribution center safety committee
- Retained all International Logistics Specialist responsibilities

November 2011-January 2017 Hospira, a Pfizer company, Stone Mountain, Georgia

International Logistics Specialist

- Executed highly regulated and refrigerated product shipments in 2015 with zero product loss
- Implemented and led employee group meetings for 4 areas of warehouse focused on improving accuracy and productivity. Parcel order shipping errors(less than 150 lbs) were reduced by 62% and "less than full case" errors were reduced by 44%
- Researched and implemented carrier changes for Puerto Rico shipments resulting in cost savings of over 30 %.
- Successfully communicated with the Drug Enforcement Administration over 5 years strengthening relationship and developing rapport
- Obtained a high level of SAP comprehension resulting in becoming the on-site SAP trainer and problem solver
- Assumed responsibilities of Information Security Officer in March 2016

May 2010-November 2011 Hospira Inc., Stone Mountain, Georgia

Controlled Drug Vault Supervisor

- Supervised eight vault employees
- Created Microsoft Excel based daily inventory spreadsheet resulting in the elimination of human count errors and reduction of inventory reconciliation time

- Improved process of checking DEA issued form 222 for customer orders allowing for reduction in misplaced 222 forms and ability for employees to be cross-trained
- Managed daily operations in all aspects of shipping, receiving, and product inventories
- Redesigned warehouse racking and labeling configurations to reduce product searches by 90%

September 2005-May 2010 Hospira Inc., Stone Mountain, Georgia

ARCOS Specialist/Warehouse Supervisor- ARCOS is the Automation of Reports and Consolidated Order System. This system monitors the sales of controlled substances and is reported by pharmaceutical companies to the Drug Enforcement Administration

- Verified ARCOS entries and provided quarterly reporting to the Drug Enforcement Administration
- Supervised 15 employees
- Restructured local fleet(truck/trailer) operations at the distribution center transforming failing operation into an asset; cost savings and efficiencies led to transportation department growth of 100%
- Developed new process for daily controlled drug inventories resulting in $35,000 in annual cost savings and increased accuracy

SKILLS AND ACCOMPLISHMENTS

- Proficient in Microsoft Office
- Display a high comprehension of distribution operations and SAP
- Rang the opening bell at the New York Stock Exchange with the CEO and members of the Senior Leadership Team of Hospira, Inc. in May 2014
- 10+ years managing and leading employees
- During nationwide controlled drug shortage, received 1 of 2 inter company supply chain awards given for outstanding leadership

TRAINING

- International Air Transport Association(IATA) regulations
- US Department of Transportation(DOT) regulations
- Resource Conservation and Recovery Act(RCRA) hazardous waste regulations
- General Drug Enforcement Administration(DEA), DEA Automation of Reports and Consolidated Order System(ARCOS), and DEA controlled drug exporting regulations
- Good Manufacturing Practices(GMP) compliance and Corrective Action/Preventative Action(CAPA) within GMP
- Automated Commercial Environment(ACE) system within US Customs and Border Protection
- Participated in off-campus training in communication, managing and supervising people, writing skills, finance, accounting, time management, and advanced Microsoft Excel techniques

EDUCATION

BA Economics
University of Georgia - Athens, Georgia (December 1998)

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Elanco US Inc

Address: 2500 Innovation Way City: Greenfield State: IN Zip: 46140

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: MA

Parent Company (if any): DPWN Holdings (USA), Inc.

Corporation/Organization Name: Exel Inc. dba DHL Supply Chain (USA)

Mailing Address: 360 Westar Blvd, Dept 555

City: Westerville State: OH Zip: 43082

Telephone: 614-865-8500 Email: regulatory@dhl.com

Contact Person Name: Mark A. Smolik

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Exel Inc. dba DHL Supply Chain (USA)

Facility Name

Mark A. Smolik

Print Name of Authorized Person Submitting Application

Mark A. Smolik

→ Original signature of Authorized Person (copies or stamps not accepted)

→ Date 11/28/23

Board Use Only	Date Received: 12/18/23	Amount: $1000 - check 6541850



Exel Inc. dba DHL Supply Chain (USA)

Business Description

Exel Inc. dba DHL Supply Chain (USA) has been at the forefront of innovative supply chain solutions for the life sciences and healthcare industries for 20 years. As a trusted global partner we create agile, highly responsive supply chains capable of transporting critical, sensitive and valuable products, even to the world's most rugged and remote locations.

Our extensive experience of supplying logistical solutions to the life sciences and healthcare sector has enabled us to develop specific expertise in the following areas: Vaccines, Generic Pharmaceuticals, Controlled Substances, Over The Counter (OTC) Medication, and Animal Health. For each of these areas we have experts working with our customers to optimize their supply chains.

A connected global footprint and industry expertise
With over 120 sites in 40 countries and 4,500 dedicated healthcare staff, serving 250 life sciences and healthcare customers worldwide, we're always there to offer a safe pair of hands. We have the scale and experience to implement healthcare logistics solutions across the world.

Quality and regulatory compliance
For our customers, deep sector expertise is vital to track, comprehend, and comply with essential and increasing rules and regulations for the storage, transportation and delivery of pharmaceuticals, medical equipment and patient-specific treatments.

With our Global Quality Assurance group of over 100 individuals driving operational consistency and governance we're always up to date with the latest changes in local and international regulations. Our global network provides highly controlled environments and we ensure full GxP (Good Practice) compliance from origin to destination.

Health, safety and security
We help to achieve high standards on health, safety and security through extensive training and timely monitoring. We offer consulting on global safety regulations and conduct regular inspections and process audits of our facilities.

Exel Inc.

d/b/a DHL Supply Chain (USA)
360 Westar Blvd, Westerville, OH 43082
State of Incorporation: MA
Date of Incorporation: 6/1/1983
EIN: 04-2801160

Title	*Name of Officer	Address	Telephone
Chairman, Chief Executive Officer & President	Scott Sureddin	360 Westar Boulevard, Westerville, OH 43082	614-865-8500
Chief Financial Officer & Treasurer	Scot Hofacker	360 Westar Boulevard, Westerville, OH 43082	614-865-8500
Chief Legal Officer & Secretary	Mark Smolik	360 Westar Boulevard, Westerville, OH 43082	614-865-8500

**No percentages owned*


Deutsche Post AG
(Germany)
Publicly Traded
100%
Deutsche Post DHL Beteiligungen Holding GmbH (DPBH)
(Germany)
100%
Deutsche Post DHL Beteiligungen GmbH (DPDHL Beteiligungen)
(Germany)
100%
DPWN Holdings (USA), Inc.
State of Incorporation: Ohio
100%
Exel Inc. dba DHL Supply Chain (USA)
360 Westar Boulevard
Westerville, OH 43082
(Parent Company/North America Headquarters)
State of Incorporation: Massachusetts
Corporate Officers:
Kenneth Scott Sureddin: CEO & Chairman
Scot Hofacker: CFO & VP
Mark Smolik: Chief Legal Officer

The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

Date: September 05, 2023

To Whom It May Concern :

I hereby certify that according to the records of this office,

EXEL INC.

is a domestic corporation organized on **June 01, 1983** , under the General Laws of the Commonwealth of Massachusetts. I further certify that there are no proceedings presently pending under the Massachusetts General Laws Chapter 156D section 14.21 for said corporation's dissolution; that articles of dissolution have not been filed by said corporation; that, said corporation has filed all annual reports, and paid all fees with respect to such reports, and so far as appears of record said corporation has legal existence and is in good standing with this office.

In testimony of which,
I have hereunto affixed the
Great Seal of the Commonwealth
on the date first above written.

William Francis Galvin

Secretary of the Commonwealth

Certificate Number: 23090026010

Verify this Certificate at: http://corp.sec.state.ma.us/CorpWeb/Certificates/Verify.aspx

Processed by: ili

Certificate of Registration

Certificate No. 3000010480
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Distributor (Prescription)

Drug & Device Registration
2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

EXEL INC. DBA DHL SUPPLY CHAIN (USA)
1141 E. HARRISBURG PIKE
MIDDLETOWN, PA 17057

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: February 23, 2023
Expiration Date: The Last Day of March, 2025

Susan Coble
Acting Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

RIDER

To be attached to and form part of:

Bond Number	016075066
originally dated	April 15, 2017
issued by the	LIBERTY MUTUAL INSURANCE COMPANY
originally in the amount of	$ 100,000.00
on behalf of	EXEL, INC. DBA DHL SUPPLY CHAIN (USA) (Principal)
and in favor of	THE STATE OF NEVADA (Obligee)

Now therefore, it is agreed that in consideration of the premium charged, the attached bond shall be amended as follows:

The following site location is added:

- 1141 E. Harrisburg Pike, Middletown, PA 17057

It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This Rider is to be Effective this 3rd day of November, 2023.

Signed, Sealed & Dated this 3rd day of November, 2023.

LIBERTY MUTUAL INSURANCE COMPANY
(Surety)

By: _____
Jennifer L. Jakaitis, Attorney-in-Fact

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS
Seal No. 5973

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8210339-285057**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aerie Walton, Aaron Griffin, Bartlomiej Siepierski, Christina L. Sandoval, Christopher P. Troha, Corinne Chapman, Dartonya Wright, Derek J Elston, James B. McTaggart, Jean Torres, Jennifer L. Jakaitis, Jennifer Williams, Jessica B. Dempsey, Judith A. Lucky-Eftimov, Kristin L. Hannigan, Melissa L. Fortier, Nicholas Kertesz, Rachel Fore, Richard Casas, Roger Paraison, Samantha Chierici, Sandra M. Winsted, Susan A. Welsh, Tara A. Reimer

all of the city of Chicago state of IL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 27th day of June, 2023.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 27th day of June, 2023 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 3rd day of November, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Exel Inc. dba DHL Supply Chain (USA)

Pharmacy/Wholesaler License # (if applicable) NA

Physical Address 1141 E. Harrisburg Pike

City Middletown State PA Zip 17057

Mailing Address (if different from physical address) 360 Westar Blvd, Dept 555

City Westerville State OH Zip 43082

Telephone 717-574-5644 Website www.exel.com

Licensing Company Email DHL@IQVIA.com

Section 2: Personal Information

First Scott Middle Alan Last Hile

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 1141 E. Harrisburg Pike

City Middletown State PA Zip 17057

Telephone 717-574-5644 Email scott.hile@dhl.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Penn State University		09/98-09/99	
Address	**City**	**State**	**Zip**
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Middletown Area High School		09/83-09/86	
Address	**City**	**State**	**Zip**
1155 N Union St	Middletown	PA	17057
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1992-Present	[redacted] Meadowview Ct	Harrisburg	PA	17111
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Exel Inc. dba DHL Supply Chain (USA)			2020-2023	
Business Address		**City**	**State**	**Zip**
84 Zions View Rd		Manchester	PA	17345
Phone	**Title**		**Number of Employed Hours**	
717-574-5644	General Manager		6000+	
Description of Duties				
Responsibility of startup and development of new clients coming into the Multi Client Facility, Development of relationship with Customer, Inventory Control, Quality Insurance (Licensing) and Performance Expectations (External/Internal) & Operational responsibility for Customer account.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	☐	☑
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	☐	☐
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	☐	☑
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	☐	☑
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	☐	☑
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	☐	☑
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?	☐	☑
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.	☐	☑
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	☐	☑
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☑

I, Scott Hile, **certify that as the designated representative for**

Exel Inc. dba DHL Supply Chain (USA),

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SH I am at least 21 years of age;
3. SH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Scott Hile

Print Name (First, Last)

Scott A. Hile

→ Original Signature (electronic, copies or stamps not accepted)

11/20/2023

→ Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott Hile

Print Name (First, Last)

Scott A. Hile

→ Original Signature (electronic, copies or stamps not accepted)

11/20/2023

→ Date

→ **Please have this section completed in the presence of a Notary Public.**

State of PA, ss. County of Cumberland

I, Scott A. Hile, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Scott A. Hile

Original Signature

11/20/2023

Date

Subscribed and Sworn to before me this 20th day of November 2023.

Wanda Kay McCormack

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Wanda Kay McCormack, Notary Public
Cumberland County
My commission expires April 7, 2024
Commission number 1240989
Member, Pennsylvania Association of Notaries

(Seal)

Employees

DHL Supply Chain
1141 E Harrisburg Pike
Middletown, PA 17057

Associate List	
Name	**Role**
Scott Hile	General Manager I
Trent Shaw	General Manager III
Jonah MacMillan	Operations Manager I
Chase Snavely	Supervisor
Michael Cross	Supervisor
Ned Maroney	Systems Manager
Jon Foster	Area Quality Manager
Michelle Geter	HR Manager
Eric Nace (1st)	Tasker
Pam Cyseski (1st) Pending BG/DT	Shipping Clerk
Dave Gontz (1st)	FLO
Mark Ward (1st)	FLO
Marcel Gonzalez (1st)	FLO
Jill Rishar (1st) Pending BG/DT	FLO
Tom Shaffer (1st) Pending BG/DT	FLO
Tyler Giacchino (1st)	FLO
Kimberly Huggler (1st) Pending BG/DT	FLO

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: J&B Medical Supply Co., Inc.

Physical Address: 50496 Pontiac Trail

City: Wixom State: MI Zip: 48393

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-737-0045 Website: https://www.jandbmedical.com

Name of Designated Representative (DR): Shawn Napora

Licensing Company Email: credentialing@jandbmedical.com DR Email: credentialing@jandbmedical.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: enteral, ostomy, BGM, CGM, wound care	☒ Warehouse
☒ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: EMS/EMT, jails, health facilities		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Amerisource
Address: 1 Industrial Park Dr. City: Williamston State: MI Zip: 48895

Name: Mckesson
Address: 6555 State Hwy 161 City: Irving State: TX Zip: 75039

Name: National Distribution and Contracting (NDC)
Address: 402 BNA Dr. City: Nashville State: TN Zip: 37217

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Michigan
Parent Company (if any):
Corporation/Organization Name: J&B Medical Supply Co., Inc.
Mailing Address: 50496 Pontiac Trail
City: Wixom State: MI Zip: 48393
Telephone: 800-737-0045 Email: credentialing@jandbmedical.com
Contact Person Name: Cynthia Matthews

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

J&B Medical Supply Co., Inc.

Facility Name

Mary Shaya

Print Name of Authorized Person Submitting Application

Mary Shaya

Original signature of Authorized Person (copies or stamps not accepted)

2/9/2024

Date

Board Use Only	Date Received: 2/22/24	Amount: $1000 - check 6261196

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

Officers and Directors

- Mary Shaya – 51%, President/CEO
- Fawzi B. Shaya Trust– 49%, Deceased
- Charlene Shaya, Executive VP
- Julian Shaya, Executive VP

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

J&B MEDICAL SUPPLY CO., INC.

was validly incorporated on January 12 , 1996 as a Michigan DOMESTIC PROFIT CORPORATION, and said corporation is validly in existence under the laws of this state.

This certificate is issued pursuant to the provisions of 1972 PA 284 to attest to the fact that the corporation is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS ★ Corporations, Securities & Commercial Licensing Bureau ★

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 5th day of January , 2024.

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24010116504

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

5306007104APP22



J&B MEDICAL SUPPLY CO., INC.
50496 PONTIAC TRAIL
WIXOM, MI 48393

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

Q494070

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

J&B MEDICAL SUPPLY CO., INC.
50496 PONTIAC TRAIL
WIXOM, MI 48393

LICENSE NO.
5306007104

EXPIRATION DATE
12/14/2024

23019040101

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 10/9/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Carrico Maldegen Insurance
41000 West 7 Mile Road
Suite 140
Northville MI 48167

CONTACT NAME:
PHONE (A/C, No, Ext): 248-773-7930 **FAX (A/C, No):** 248-773-7936
E-MAIL ADDRESS: cmia@carricomaldegen.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Massachusetts Bay Insurance Co	22306
INSURER B : Citizens Insurance Company of	31534
INSURER C : Travelers Insurance Company	
INSURER D : Allmerica Financial Alliance I	10212
INSURER E :	
INSURER F :	

INSURED J&BMEDI-01
J & B Medical Supply Co., Inc
50496 W Pontiac Trl
Wixom MI 48393

COVERAGES **CERTIFICATE NUMBER:** 1902710162 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			LDBD730020	10/22/2023	10/22/2024	EACH OCCURRENCE	$ 3,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Prof. Liability						MED EXP (Any one person)	$ 10,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$ 3,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$ 3,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$ 3,000,000
							Emp. Benefits	$ 1,000,000
B	AUTOMOBILE LIABILITY			A7B8119408	10/22/2023	10/22/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	X UMBRELLA LIAB X OCCUR			U7B0392122	10/22/2023	10/22/2024	EACH OCCURRENCE	$ 7,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 7,000,000
	DED X RETENTION $ 0							$
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N	N/A		WKB2097836	10/22/2023	10/22/2024	X PER STATUTE OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y						E.L. EACH ACCIDENT	$ 500,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 500,000
							E.L. DISEASE - POLICY LIMIT	$ 500,000
C	Crime			107847335	5/13/2023	5/13/2024	Employee Dishonesty Deductible	$5,000,000 $50,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
50496 W Pontiac Trail, Wixom MI 48393 Corporate Headquarters Warehouse. Evidence of Insurance - Property Coverage provided by B) Citizens Insurance RBH2097796, Blanket building Limit $10,755,212, Blanket Contents Limit. $15,131,000, Blanket Business Income $34,000,000.

CERTIFICATE HOLDER
J&B Medical Supply Co. Inc
50496 W Pontiac Trail
Wixom MI 48393

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. B150043668

Application/License No. _____

Mary E. Shaya (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 50496 Pontiac Trl, Wixom, MI 48393-2088 (Address of Applicant/Principal), as PRINCIPAL, and Old Republic Surety Company (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 18500 W Corporate Dr, Ste 170, Brookfield, WI 53045 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 3/18/2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of March, 20 24.

APPLICANT/PRINCIPAL

COMPANY
Mary E. Shaya

Mary Shaya
Authorized Representative

CYNTHIA RENEE HUGHES
Notary Public – State of Michigan
County of Livingston
My Commission Expires Dec 3, 2029
Acting in the County of

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY

Old Republic Surety Company

Surety Company's Representative

Barry W. Berman, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

OLD REPUBLIC SURETY COMPANY

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That OLD REPUBLIC SURETY COMPANY, a Wisconsin stock insurance corporation, does make, constitute and appoint: Anne Solomko Of NOVI, Michigan

its true and lawful Attorney(s)-in-Fact, with full power and authority, not exceeding $10,000,000, for and on behalf of the company as surety, to execute and deliver and affix the seal of the company thereto (if a seal is required), bonds, undertakings, recognizances or other written obligations in the nature thereof, ***(other than bail bonds, bank depository bonds, mortgage deficiency bonds, mortgage guaranty bonds, guarantees of installment paper and note guaranty bonds, self-insurance workers compensation bonds guaranteeing payment of benefits, asbestos abatement contract bonds, waste management bonds, hazardous waste remediation bonds or black lung bonds),*** as follows: Effective Date of Change: 03/18/2024

Bond Number: B150043668 Bond Amount: One Hundred Thousand Dollars $ 100,000.00
Principal Name: Mary E. Shaya
Obligee Name: NV State Board of Pharmacy, Nevada

and to bind OLD REPUBLIC SURETY COMPANY thereby, and all of the acts of said Attorneys-in-Fact, pursuant to these presents, are ratified and confirmed. This appointment is made under and by authority of the board of directors at a special meeting held on February 18, 1982.

This Power of Attorney is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the board of directors of the OLD REPUBLIC SURETY COMPANY on February 18,1982.

RESOLVED that the president, any vice president or assistant vice president, in conjunction with the secretary or any assistant secretary, may appoint attorneys-in-fact or agents with authority as defined or limited in the instrument evidencing the appointment in each case, for and on behalf of the company to execute and deliver and affix the seal of the company to bonds, undertakings, recognizances, and suretyship obligations of all kinds; and said officers may remove any such attorney-in-fact or agent and revoke any Power of Attorney previously granted to such person.

RESOLVED FURTHER that any bond, undertaking, recognizance, or suretyship obligation shall be valid and binding upon the Company

(i) when signed by the president, any vice president or assistant vice president, and attested and sealed (if a seal be required) by any secretary or assistant secretary; or

(ii) when signed by the president, any vice president or assistant vice president, secretary or assistant secretary, and countersigned and sealed (if a seal be required) by a duly authorized attorney-in-fact or agent; or

(iii) when duly executed and sealed (if a seal be required) by one or more attorneys-in-fact or agents pursuant to and within the limits of the authority evidenced by the Power of Attorney issued by the company to such person or persons.

RESOLVED FURTHER that the signature of any authorized officer and the seal of the company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the company; and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, OLD REPUBLIC SURETY COMPANY has caused these presents to be signed by its proper officer, and its corporate seal to be affixed this 26th day of March, 2024.

OLD REPUBLIC SURETY COMPANY

Karen J. Haffner
Assistant Secretary

Alan Pavlic
President

STATE OF WISCONSIN, COUNTY OF WAUKESHA - SS

On this 26th day of March, 2024, personally came before me, Alan Pavlic and Karen J. Haffner, to me known to be the individuals and officers of the OLD REPUBLIC SURETY COMPANY who executed the above instrument, and they each acknowledged the execution of the same, and being by me duly sworn, did severally depose and say: that they are the said officers of the corporation aforesaid, and that the seal affixed to the above instrument is the seal of the corporation, and that said corporate seal and their signatures as such officers were duly affixed and subscribed to the said instrument by the authority of the board of directors of said corporation.

Kathryn R. Pearson
Notary Public

My Commission Expires: 09/28/2026
(Expiration of notary's commission does not invalidate this instrument)

CERTIFICATE

I, the undersigned, assistant secretary of the OLD REPUBLIC SURETY COMPANY, a Wisconsin corporation, CERTIFY that the foregoing and attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolutions of the board of directors set forth in the Power of Attorney, are now in force.

0465186

Signed and sealed at the City of Brookfield, WI this 26th day of March, 2024.

Karen J. Haffner
Assistant Secretary

ORSC 22282 (3-06)

CONST BONDING SPECIALISTS LLC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG J&B Medical Supply Co., Inc MDEG License # (if applicable) _____

Physical Address 50496 Pontiac Trail

City Wixom State MI Zip 48393

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-737-0045 Website www.jandbmedical.com

Licensing Company Email credentialing@jandbmedical.com

Section 2: Personal Information

First Shawn Middle M Last Napora

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] John St

City Wayne State MI Zip 48184

Telephone 800-737-0045 Email credentialing@jandbmedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cambridge A.E		3/96-3/96	
Address	**City**	**State**	**Zip**
28522 Cambridge St	Garden City	MI	48135
Diploma/Degree obtained, if any			
G.E.D			

School Name		From - To (MM/YY – MM/YY)	
Chadsey High School		09/92-06/95	
Address	**City**	**State**	**Zip**
5335 Martin St	Detroit	MI	48210
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/06-present	[redacted]John St	Wayne	MI	48184
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
J&B Medical Supply Co., Inc			06/20-present	
Business Address		**City**	**State**	**Zip**
50496 Pontiac Trail		Wixom	MI	48393
Phone	**Title**		**Number of Employed Hours**	
800-737-0045	Warehouse Supervisor		7360+	
Description of Duties				
Managment of all warehouse employees and daily activities and operations of the warehouse. Control of inventory, inbound, outbound. Enforcing of policies and procedures.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Shawn M Napora, **certify that as the MDEG Administrator for**

J&B Medical Supply Co., Inc,

that I (initial that you have read and meet the following requirements):

1. SMN Have a high school diploma or its equivalent;
2. SMN Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SMN Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SMN Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shawn M Napora
Print Name (First, Last)

S. M. N.
Original Signature (electronic, copies or stamps not accepted)

3/1/2024
Date

Board Use Only	Date Received: 3/3/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler J&B Medical Supply Co., Inc.

Physical Address 50496 Pontiac Trail

City Wixom State MI Zip 48393

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-737-0045 Website https://www.jandbmedical.com

Licensing Company Email credentialing@jandbmedical.com

Section 2: Personal Information

First Shawn Middle M Last Napora

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] John St

City Wayne State MI Zip 48184

Telephone [redacted] Email Snapora@jandbmedical.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: 10/27/1999 to: 10/27/2003

Military Occupation/Specialty Chemical,Biological and Radio-logical Defense specialist

Branch: ☐ Army/Reserves ■ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cambridge A.E.		03/96-03/96	
Address	City	State	Zip
28522 Cambridge st.	Garden City	MI	48135
Diploma/Degree obtained, if any			
G.E.D			

School Name		From - To (MM/YY – MM/YY)	
Chadsey High School		09/92-06/95	
Address	City	State	Zip
5335 Martin st.	Detroit	MI	48210
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/06-Present	[redacted] John st.	Wayne	MI	48184
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials SMN

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
J&B Medical Supply Co. Inc.			06/20-Present	
Business Address		**City**	**State**	**Zip**
50496 Pontiac Trail		Wixom	MI	48393
Phone	**Title**		**Number of Employed Hours**	
(800) 737-0045	Warehouse Supervisor		7360+	
Description of Duties				
Management of all warehouse employee's and Safety policies. Control of warehouse inventory inbound and outbound.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Applicant's initials SMN

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Shawn M. Napora, **certify that as the designated representative for**

J&B Medical Supply Co. Inc.,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Shawn M. Napora

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Feb 9, 2024

Date

Applicant's initials SMN

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shawn M. Napora

Print Name (First, Last)

Original Signature (electronic/copies or stamps not accepted)

Feb 9, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Oakland

I, Shawn Napora, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Feb 9, 2024

Date

Subscribed and Sworn to before me this 9th day of February 2024

Notary Public Signature

CYNTHIA RENEE HUGHES
Notary Public – State of Michigan
County of Livingston
My Commission Expires Dec 3, 2024
Acting in the County of OAKLAND

(Seal)

Applicant's initials SMN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site J&B Medical Supply Co., Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 50496 Pontiac Trail

City Wixom State MI Zip 48393

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-737-0045 Website https://www.jandbmedical.com

Licensing Company Email credentialing@jandbmedical.com

Section 2: Personal Information

First Mary Middle _____ Last Shaya

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]ontiac Trail

City Wixom State MI Zip 48393

Telephone 800-737-0045 Email credentialing@jandbmedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) N/A		
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) N/A		
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) N/A		

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Madonna University		09/67-12/67	
Address	**City**	**State**	**Zip**
36600 Schoolcraft Rd	Livonia	MI	48150
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Henry Ford High School		8/63-5/67	
Address	**City**	**State**	**Zip**
20000 Evergreen Rd	Detroit	MI	48219
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10+ years	[redacted] West Shore Dr	Orchard Lake	MI	48324
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
J&B Medical Supply Co., Inc.			1994-present	
Business Address		**City**	**State**	**Zip**
50496 Pontiac Trai		Wixom	MI	48393
Phone	**Title**			
800-737--0045	President-Owner			

Description of Duties

Leadership and development of corporate structure, maintains everyday business overview, initiates company policy, responsible for management and organization of over 100 employees, controls financial transactions.

Business Name			From - To (MM/YY – MM/YY)	
Labcorp			1998-2003	
Business Address		**City**	**State**	**Zip**
N/A				
Phone	**Title**			

Description of Duties

Managed and directed several sales reps, trained new hires in sales, monitored sales accounts, created procedures for maintaining vendor relationships.

Business Name			From - To (MM/YY – MM/YY)	
Universal Standard			1993-1998	
Business Address		**City**	**State**	**Zip**
N/A				
Phone	**Title**			

Description of Duties

Conducted business-to-business sales representing multiple product lines, established new customer base, generated sales leads, trained/mentored new reps.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mary Shaya
Print Name (First, Last)

Mary Shaya
Original Signature (electronic, copies or stamps not accepted)

2/9/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Oakland

I, Mary Shaya, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Mary Shaya
Original Signature

2/9/2024
Date

Subscribed and Sworn to before me this 9 day of February 2024

Cynthia Hughes
Notary Public Signature

CYNTHIA RENEE HUGHES
Notary Public – State of Michigan
County of Livingston
My Commission Expires Dec 3, 2024
Acting in the County of Oakland

(Seal)

Full List of warehouse employees

Name ▲
Banister, Daniel
Banister, Mark
Briggs, Blake
Burgess, Malina
Centeno, Kevin
Centeno, Marco
Centeno, Victor
Chapdelaine, Tina
Chicas Portillo, Olga
Clark, Anthony
Karrumi, Eric
Karrumi, Jon-Luke
Kendra, Richard
Kotcher, Robert
Linares, Nathan
Llanes, Robert
Lobbestael, Drew
Madrid, James
Marvin, Alexander
McDonald, Jeff
Stanley, Cameron
Swain, Damon
Swift, Jonathan
Thoms, Michael
Tigrera-Barrios, Willian
Van Blaricum, Paul
Vonreichbauer, Ryan
Ward, Jennifer
Williams, DeAndre
Zawacki, Sophie

Dilldine, Kerry
Dixon, Sean
Dorion, Lakin
Dorsey, Derrick
Dorsey, Rodrick
Ford, Hannibul
Frank, Erik
George, Joress
Gordy, Haley
Goyette, Andre
Miller, Christopher
Moreira, Angela
Napora, Shawn
Naumoff, Steven
Orosey, Nicholas
Owens, Mark
Peters, Craig
Plata III, Santiago
Pollard, Philip
Pribik, Alex

Goyette, Christopher
Handley, Adrian
Hawkins, Drodrick
Hibler, Lacondre
Hughes, Joshua
Jackson, Marcie
Johnson, Antoine
Kaier, Justyn
Karrumi, Angelina
Karrumi, Dilyla
Pullano, Steven
Pullen, Keith
Quarles, Marcus
Rubio, Kayleen
Sankareh, Alhagie Malang
Sawdon, Keith
Seaborn, Rodney
Smith, John
Smith, Trokon
Stalker, John

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: TS Pharm Inc.

Physical Address: 9770 Research drive

City: Irvine State: CA Zip: 92618

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 949-727-9666 Website: TS Pharm Inc.

Name of Designated Representative (DR): Taher Sheybani

Licensing Company Email: www.tspharminc.com DR Email: Ts1@tspharm.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Wholesaler distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Pfizer Inc.(Hospira)
Address: P.O Box 417510 City: Boston State: MA Zip: 02241

Name: Xiromed
Address: 180 Park Ave. Suite 101 City: Florham park State: NJ Zip: 07932

Name: Advance Pharmaceuticals (NY)
Address: 895 Waverly Avenue City: Hottsville State: NY Zip: 11742

Name: Sciegen Pharmaceuticals
Address: 89 Arkay Drive City: Hauppauge State: NY Zip: 11788

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California Board of Pharmacy
Parent Company (if any):
Corporation/Organization Name: TS Pharm Inc.
Mailing Address: 9770 Research Drive
City: Irvine State: CA Zip: 92618
Telephone: 949-727-9666 Email: angel@tspharm.com
Contact Person Name: Archangel Lanuza

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

TS Pharm Inc.

Facility Name

Taher Sheybani

Print Name of Authorized Person Submitting Application

T. Sheybani

Original signature of Authorized Person (copies or stamps not accepted)

4/24/2024

Date

Board Use Only	Date Received: 4/29/24	Amount: $1000 check 2351



TS Pharm Inc.

Taher Sheybani

Managing Director

50% owner

Yassi Fouladi

President

50% owner

Email address: ts1@tspharm.com

9770 Research Drive

Irvine, California 92618

Tel# (949) 727-9666

Fax# (949)727-3666

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	TS PHARM, INC.
Entity No.:	2743370
Registration Date:	04/20/2005
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of September 25, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 147562936

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal License

Wholesale Drug Permit

LICENSE NO. WLS 3972
RECEIPT NO. 31880564

VALID UNTIL AUGUST 01, 2024

T S PHARM
9770 RESEARCH DRIVE
IRVINE CA 92618

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

)7/11/23
)7/11/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RT0555322	11-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	10-11-2023

TS PHARM INC.
9770 RESEARCH DR
IRVINE, CA 926184327

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RT0555322	11-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
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TS PHARM INC.
9770 RESEARCH DR
IRVINE, CA 926184327

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 72BSBJE9284

Application/License No. _____

TS Pharm Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 9770 Research Drive, Irvine, CA 92618 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 200 Colonial Center Pkwy, Lake Mary, FL 32746 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 20, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 19th day of April, 2024.

APPLICANT/PRINCIPAL

TS Pharm Inc

Authorized Representative

TAHER SHEYBANI

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Courtney Gomez , Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Jessica Ciccone
Witness

Christina Miller
Witness

Countersigned by:

Paul Ricks
Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: PRIME INSURANCE SERVICES INC
Agency Code: 72-186083

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Courtney Gomez
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 72BSBJE9284
Naming TS Pharm Inc as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of April 19, 2024.

Signed and sealed in Lake Mary, Florida.

Keith Dozois

Keith D. Dozois, Assistant Vice President

Hartford Fire Insurance Company

THE HARTFORD

Date: April 19, 2024

Agency Code: 72 186083

PRIME INSURANCE SERVICES INC
9891 IRVINE CENTER DRIVE 160
IRVINE CA, 92618

OBLIGEE:
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
RENO, NV 89521

Attn: Bond Department

Insured / Principal: TS Pharm Inc
Policy / Bond #: 72BSBJE9284
Account Name/Number: TS Pharm, Inc. 72M100746441
Policy Term: April 20, 2024 - April 20, 2025
Type of Policy: Surety - License & Permit
Billing Term: Annual
Billing Type: Direct Bill
Transaction Type: New Bond
Transaction Effective Date: April 20, 2024
Bond Limit: $100,000

Agent's Advice of Premium for Fidelity and Surety Bonds

Premium		
$ 1,000		

COMMENTS:

Premium will be included in your usual Agency Accounting statement or Direct Bill notification.
If you have any questions regarding this transaction, please contact your Hartford Bond Center.



Producer Compensation Notice
To The Principal

You can review and obtain information on The Hartford's producer compensation practices at www.thehartford.com or at 1-800-592-5717.

© 2007, The Hartford

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: TS Pharm Inc.

Pharmacy/Wholesaler License # (if applicable): California WLS 3972

Physical Address: 9770 Research Drive

City: Irvine State: CA Zip: 92618

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (949) 727-9666 Website: www.tspharm.com

Licensing Company Email: info@tspharm.com

Section 2: Personal Information

First: Taher Middle: Last: Sheybani

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]Altino

City: Newport Coast State: CA Zip: 92657

Telephon[redacted] Email: ts1@tspharm.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Maryland School of Pharmacy		08/1980 - 05/1984	
Address	**City**	**State**	**Zip**
20 N. Pine Street	Baltimore	MD	21201
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Maryland College Park		08/1979 - 07/1980	
Address	**City**	**State**	**Zip**
	College Park	MD	20742
Diploma/Degree obtained, if any			
Pre-Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Taunton School		09/1974 - 07/1978	
Address	**City**	**State**	**Zip**
	Taunton, England		
Diploma/Degree obtained, if any			
O Levels and A Levels			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2021 - Present	[redacted]Altino	Newport Coast	CA	92657
09/2020 - 11/2021	[redacted]via Cristallo	Newport Coast	CA	92657
06/2013 - 09/2020	[redacted]Somerset Lane	San Juan Capistrano	CA	92675

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
TS Pharm Inc.			08/2001 - Present
Business Address	**City**	**State**	**Zip**
9770 Research Drive	Irvine	CA	92618
Phone	**Title**	**Number of Employed Hours**	
(949) 727-9666	Managing Director	40,000	
Description of Duties			
Prescribe			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Taher Sheybani, Pharm.D.

[redacted] Research Drive, Irvine, CA 92618, USA | [redacted]

Objective

- To inform all parties of my background, experience and education.

Education

DOCTOR OF PHARMACY | MAY 1984 | UNIVERSITY OF MARYLAND

EXPERIENCE

MANAGING DIRECTOR | TS PHARM INC. | JUNE 2005 - PRESENT

- Running day to day business
- Increasing the business by 4 fold in 8 years
- Expanding territories where the company is active

MANAGING DIRECTOR | TS MED INTERNATIONAL | JAN 1996 - JUNE 2005

- Starting the company
- Participating in USAID tenders
- Representing manufacturers
- Finding new ways to grow the company

ASSISTANT PROFESSOR OF CLINICAL PHARMACY | NORRIS CANCER CENTER | JAN 1989 - AUG 1992

- Clinical Pharmacist working with Cancer patients at Norris Cancer Center
- Participating in rounds with oncologists
- Helping formulate TPN preparations
- Consultation on drug dosing
- Dispensing of pharmaceuticals
- CPR/ACLS Certification
- Lecturer at the USC Pharmacy School on Emergency Medications

CLINICAL PHARMACIST| MEMORIAL SLOAN-KETTERING CANCER CENTER | AUG 1985 – DEC 1988

- Clinical Pharmacist at the Special Care Unit of the Hospital
- Participating in daily physician rounds

CLINICAL PHARMACIST | JOHN HOPKINS CANCER CENTER | AUG 1984 – JUL 1985

- Clinical Pharmacist at the Oncology Center of Johns Hopkins Hospital
- Participating in daily Physician Rounds

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Taher Sheybani, **certify that as the designated representative for**

TS Pharm Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Taher Sheybani

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/4/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Taher Sheybani

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/4/2024

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Taher Sheybani, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/4/2024

Date

Subscribed and Sworn to before me this 4 day of April 2024.

Notary Public Signature

CALI YANG
Notary Public - California
Orange County
Commission # 2391208
My Comm. Expires Feb. 16, 2026

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site TS Pharm Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 9770 Research Drive

City Irvine State CA Zip 92618

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (949) 727-9666 Website www.tspharm.com

Licensing Company Email info@tspharm.com

Section 2: Personal Information

First Taher Middle _____ Last Sheybani

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] Research Drive

City Irvine State CA Zip 92618

Telephone [redacted] Email ts1@tspharm.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Maryland at Baltimore		08/1980 - 05/1984	
Address	**City**	**State**	**Zip**
20 N. Pine Street	Baltimore	MD	21201
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Maryland College Park		08/1979 - 05/1980	
Address	**City**	**State**	**Zip**
	College Park	MD	20742
Diploma/Degree obtained, if any			
Pre-Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Taunton School		09/74 - 06/79	
Address	**City**	**State**	**Zip**
Staplegrove Road	Taunton	Somerset	UK
Diploma/Degree obtained, if any			
O levels and A Levels			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/21 - Present	[redacted]Altino	Newport Coast	CA	92657
09/20 - 11/21	[redacted]ia Cristallo	Newport Coast	CA	92657
07/13 - 09/20	[redacted]Somerset Lane	San Juan Capistrano	CA	92675
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
TS Pharm Inc.			04/05 - Present
Business Address	**City**	**State**	**Zip**
9770 Research Drive	Irvine	CA	92618
Phone	**Title**		
(949) 727-9666	Managing Director		
Description of Duties			
Manage the whole operation of TS Pharm Inc.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/24/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TAHER SHEYBANI
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/24/2024
Date

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, TAHER SHEYBANI, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/24/2024
Date

Subscribed and Sworn to before me this 24 day of April 2024

Notary Public Signature

CALI YANG
COMM # 2391208
ORANGE County
California Notary Public
Comm Exp Feb. 16, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site TS Pharm Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 9770 Research Drive

City Irvine State CA Zip 92618

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (949) 727-9666 Website www.tspharm.com

Licensing Company Email info@tspharm.com

Section 2: Personal Information

First Yassamin Middle _____ Last Fouladi

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]esearch Drive

City Irvine State CA Zip 92618

Telephone [redacted] Email yfs@tspharm.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State University - Northridge		08/86 - 05/88	
Address	**City**	**State**	**Zip**
18111 Nordhoff Street	Northridge	CA	91330
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Santa Monica College		08/84 - 05/86	
Address	**City**	**State**	**Zip**
1900 Pico Boulevard	Santa Monica	CA	90405
Diploma/Degree obtained, if any			
AA Degree			

School Name		From - To (MM/YY – MM/YY)	
Le Lycee Francais de Los Angeles		08/81 - 05/84	
Address	**City**	**State**	**Zip**
3261 Overland Avenue	Los Angeles	CA	90034
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/21 - Present	[redacted]Altino	Newport Coast	CA	92657
09/20 - 11/21	[redacted]ia Cristallo	Newport Coast	CA	92657
07/13 - 09/20	[redacted]Somerset Lane	San Juan Capistrano	CA	92675
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
TS Pharm Inc.			09/11 - Present
Business Address	**City**	**State**	**Zip**
9770 Research Drive	Irvine	CA	92618
Phone	**Title**		
(949) 727-9666	President		
Description of Duties			
Human Resources - Operations - Sales and Marketing			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

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Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Yassi Fouladi
Original Signature (electronic, copies or stamps not accepted)

4/24/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yassamin Fouladi
Print Name (First, Last)

Yassi Fouladi
Original Signature (electronic, copies or stamps not accepted)

4/24/24
Date

Please have this section completed in the presence of a Notary Public.

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California, ss. County of Orange

I, Yassamin Fouladi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Yassi Fouladi
Original Signature

4/24/24
Date

Subscribed and Sworn to before me this 24 day of April 2024

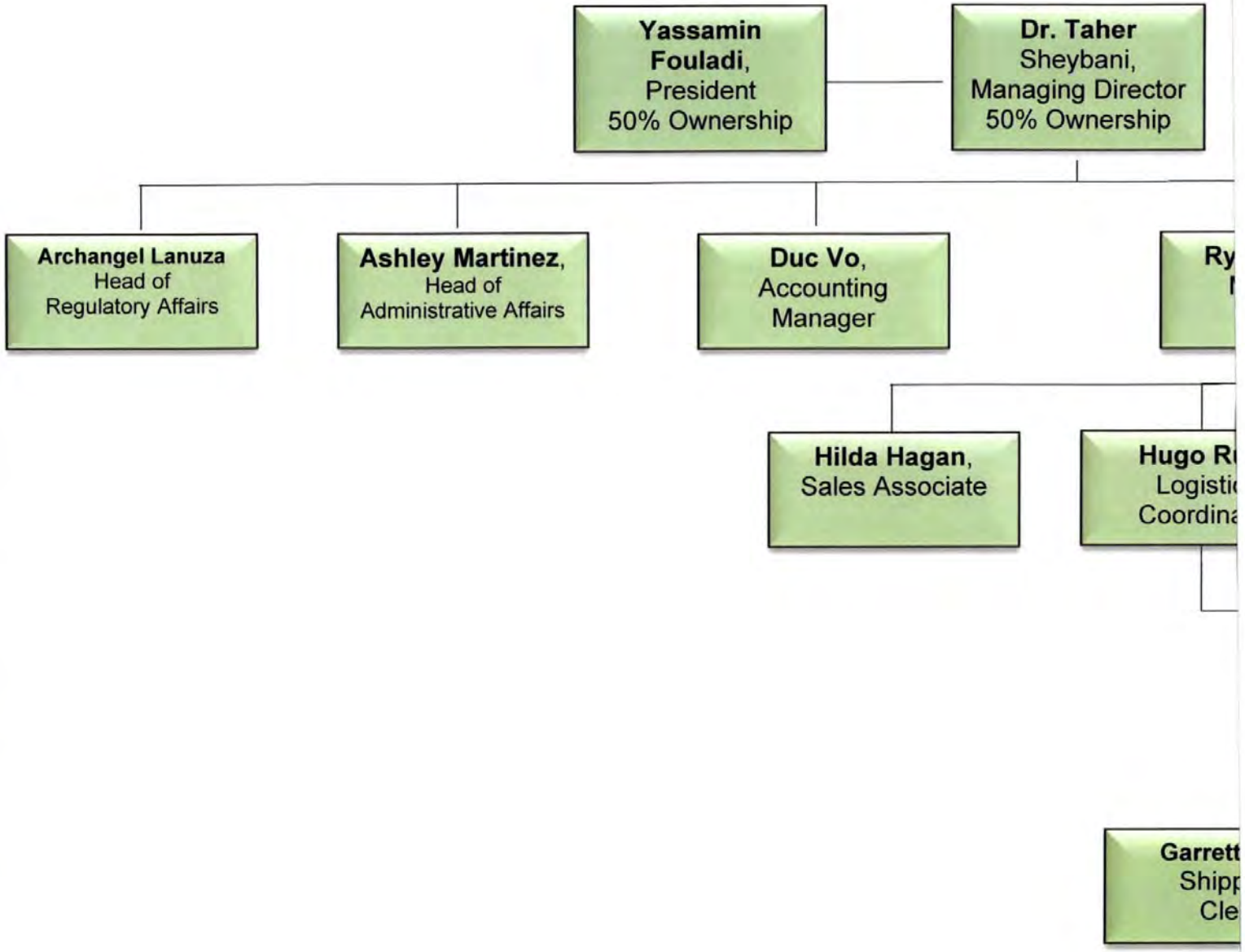
Notary Public Signature

CALI YANG
COMM # 2391208
ORANGE County
California Notary Public
Comm Exp Feb. 16, 2026

(Seal)

TS Pharm Organizatio

FEID: 20-2784334



4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☑ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: INSTACARE PHARMACY

Physical Address: [redacted] 720 E Charleston

City: ~~HENDERSON~~ Las Vegas State: NV Zip: ~~89052~~ 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-807-2049 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-202-0072 Contact Email: Rubinarafi2388@gmail.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): SAQIB NABEEL BUTT

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 13208

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: RUBINA S BUTT	NV Pharmacist Registration #: 13208
Name: AYESHA AFTAB	NV Pharmacist Registration #: 20466
Name: SAQIB N BUTT	NV Pharmacist Registration #: 12364
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEVADA

Parent Company (if any): VITALCARE PHARMA

Corporation/Organization Name: INSTACARE PHARMACY

Mailing Address: 1293 IMPERIA DRIVE

City: HENDERSON State: NV Zip: 89052

Telephone: 702-807-2049 Email: Rubinamafi238@gmail.com

Contact Person Name: RUBINA S BUTT

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the OWNER / PHARMACIST (title) for INSTACARE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

RUBINA S BUTT

Print Name of Authorized Person

Rubina S Butt

Original signature of Authorized Person (copies or stamps not accepted)

1/23/24

Date

TONI LAIRD-WISE
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 11-20-27
Certificate No: 15-3393-1

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, RUBINA S BUTT hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OWNER / PHARMACIST (title) for INSTACARE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Rubina S Butt

Signature

State of Nevada County of Clark

SUBSCRIBED AND SWORN TO

Before me, a notary public this 23 day of January, 2024

Notary Public

TONI LAIRD-WISE
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 11-20-27
Certificate No: 15-3393-1

Section I: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LICENSED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: SAQIB N BUTT Pharmacist Registration #: 12364

Pharmacy Name: INSTACARE PHARMACY

Initial each statement below to indicate you have read and agree with the following:

SB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

SB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

SB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

SB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

SB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Saqib N Butt
Original signature of Managing Pharmacist (copies or stamps not accepted)

1/23/24
Date

1) LIST OF OFFICERS AND DIRECTORS — RUBINA S BUTT

2) LIST OF STOCKHOLDERS — RUBINA S BUTT

3) STOCKHOLDERS HOLD 10% OR MORE SHARES — RUBINA S BUTT 100%.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RUBINA S BUTT

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Rubina S Butt

Original signature of Authorized Person (copies or stamps not accepted)

1/23/24

Date

Board Use Only	Date Received: 2/22/24	Amount: $500 – check 5701

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler INSTACARE PHARMACY

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 1293 IMPERIA DR

City HENDERSON State NV Zip 89052

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702 807 2049 Website _____

Licensing Company Email _____

Section 2: Personal Information

First RUBINA Middle S Last BUTT

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] IMPERIA DR

City HENDERSON State NV Zip 89052

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF PUNJAB		1985 - 1989	
Address	**City**	**State**	**Zip**
PUNJAB	LAHORE		
Diploma/Degree obtained, if any			
BACHELORS OF PHARMACY			
School Name		**From - To (MM/YY – MM/YY)**	
CONVENT OF JESUS AND MARY		1970 - 1984	
Address	**City**	**State**	**Zip**
LAHORE PAKISTAN			
Diploma/Degree obtained, if any			
GRADUATE DEGREE			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
3/2018 - PRESENT	[redacted] IMPERIA DR	HENDERSON	NV	89052
4/98 - 3/2018	[redacted] BOZEMAN DR	HENDERSON	NV	89012
2/96 - 4/98	[redacted] WHITNEY RANCH #414	HENDERSON	NV	89014
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
DRUG PLUS PHARMACY			4/2009 – PRESENT
Business Address	**City**	**State**	**Zip**
1590 W HORIZON RIDGE PKWAY #130	HENDERSON	NV	89012
Phone	**Title**		
702-834-8152	PHARMACY MANAGER / OWNER		

Description of Duties

FILLING, TYPING, TAKING VERBAL ORDERS COUNSELING
FILLING. DISPENSING, VERIFYING ORDERING.

Business Name			From - To (MM/YY – MM/YY)
SMITHS PHARMACY			4/05 – 4/2009
Business Address	**City**	**State**	**Zip**
2385 E WINDMILL LN	LAS VEGAS	NV	89123
Phone	**Title**		
702-837-0813	PHARMACY MANAGER		

Description of Duties

FILLING, TYPING, COUNSELLING, TAKING VERBAL ORDERS DISPENSING, VERIFYING.

Business Name			From - To (MM/YY – MM/YY)
RALEYS / SMITHS PHARMACY			8/1999 – 4/2005
Business Address	**City**	**State**	**Zip**
55 S VALLE VERDE DR	HENDERSON	NV	89012
Phone	**Title**		
702-837-6117	Rx MANAGER		

Description of Duties

FILLING, TYPING, COUNSELLING, TAKING VERBAL ORDERS, DISPENSING VERIFYING.

Business Name			From - To (MM/YY – MM/YY)
COSTCO 673			
Business Address	**City**	**State**	**Zip**
791 MARKS ST	HENDERSON	NV	89014
Phone	**Title**		
702-352-2080	RELIEF PHARMACIST		

Description of Duties

FILLING, TYPING, COUNSELLING, TAKING VERBAL ORDERS DISPENSING VERIFYING.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RUBINA BUTT

Print Name (First, Last)

Rubina S Butt — 2/20/2024.

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Rubina S Butt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Rubina S Butt — 2/20/2024.

Original Signature — **Date**

Subscribed and Sworn to before me this 20 day of February, 2024.

Notary Public Signature

TONI LAIRD-WISE
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 11-20-27
Certificate No: 15-3393-1

(Seal)

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

VitalCare Pharma

Nevada Business Identification # NV20243011228
Expiration Date: 01/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot he waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/23/2024.

[redacted]

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202401234285302
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC CORPORATION (78) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **VitalCare Pharma** did, on 01/23/2024, file in this office the original Articles of Incorporation-For-Profit that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/23/2024.

[redacted]

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202401234285301
You may verify this certificate online at http://www.nvsos.gov

4FF

RECEIVED 5/20/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA # FQ6034350
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH 03563		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: QHR Pharmacy

Physical Address: 765 N. Nellis Blvd #7

City: Las Vegas State: NV Zip: 89110

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-331-6388 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-331-7791 Contact Email: qhrnellis89110@yahoo.com

Website: QHRpharmacylv.com

Nevada Business License # (if applicable) 664-02521

Supervising/Managing Pharmacist Name (NRS 639.220): Teqcst Tilahun

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20171

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Tegest Tilahun	NV Pharmacist Registration #: 20171
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Leandro Seto

Business Name: BHR Pharmacy

Business Address: 765 N. Nellis Blvd #7

City: Las Vegas State: NV Zip: 89110

Telephone: [redacted] Email: [redacted]

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for QHR Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Leandro Seto

Print Name of Authorized Person

Leandro Seto

Original signature of Authorized Person (copies or stamps not accepted)

05/06/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Leandro Seto hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner (title) for QHR (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Leandro Seto
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 6th day of May, 2024

Rosa Sedo
Notary Public

ROSA A. SEDO
Notary Public, State of Nevada
Appointment No. 03-83716-1
My Appt. Expires May 28, 2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: TEGEST TILAHUN Pharmacist Registration #: 20171

Pharmacy Name: QHR PHARMACY

Initial each statement below to indicate you have read and agree with the following:

✓ I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

✓ I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

✓ I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

✓ I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

✓ I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		X

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tegest Tilahun

Original signature of Managing Pharmacist (copies or stamps not accepted)

5/3/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Leandro SETO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

05/06/24

Date

Board Use Only	Date Received: 5/20/24	Amount: $500-ck 104

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler QHR Pharmcy

Pharmacy/Wholesaler License # (if applicable) PH 03563

Physical Address 765 N nellis Blvd.

City Las Vegas State NV Zip 89110

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-331-6388 Website qhrpharmacylv.com

Licensing Company Email _____

Section 2: Personal Information

First Tegest Middle _____ Last Tilahun

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Montello Ave.

City Las Vegas State NV Zip 89110

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Massachusetts College of Pharmacy and Health Sciences (MCPHS)			09/2003-06/2006	
Address		City	State	Zip
19 Foster St.		Worcester	MA	01608
Diploma/Degree obtained, if any				
Pharm.D				
School Name			From - To (MM/YY – MM/YY)	
Concordia University			08/1986-06/1990	
Address		City	State	Zip
1455 de Maisonneuve Blvd.		Montreal, Canada		
Diploma/Degree obtained, if any				
B.Sc - Biochemistry				
School Name			From - To (MM/YY – MM/YY)	
Vanier College			08/1984-06/1986	
Address		City	State	Zip
821 Avenue Sainte-Croix		Montreal, Canada		
Diploma/Degree obtained, if any				
DCS - Health science				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2022 - present	[redacted] Montello Ave.	Las Vegas	NV	89110
08/2018 - 09/2022	[redacted] Carnation Meadow St.	Las Vegas	NV	89130
09/2013 - 07/2018	E Mississippi Ave.	Denver	CO	80247
06/2006 - 09/2013	[redacted] 16th St. NW	Washington	DC	20006
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
QHR Pharmacy			09/2022 - present
Business Address	**City**	**State**	**Zip**
765 N Nellis Blvd.	Las Vegas	NV	89110
Phone	**Title**	**Number of Employed Hours**	
702-331-6388	PIC	3,760	
Description of Duties			
Overseeing the daily operations of the pharmacy, maintaining records according to fedral & state laws, verifing & dispensing medications, providing medication counseling to patients/clients			

Business Name			From - To (MM/YY – MM/YY)
CVS Pharmacy			09/2007 - 08/2013
Business Address	**City**	**State**	**Zip**
2240 M Street	Washington	DC	20037
Phone	**Title**	**Number of Employed Hours**	
202-296-9876	Staffpharmacist	12, 500	
Description of Duties			
Verfing + dispensing medications, providing medication counseling to patients/clients.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Tegest Tilahun, **certify that as the designated representative for**

QHR,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. Yes I am at least 21 years of age;
3. Yes I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. Yes I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. Yes I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. Yes I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. Yes I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Tegest Tilahun

Print Name (First, Last)

Tegest Tilahun

Original Signature (electronic, copies or stamps not accepted)

T.T 06/12/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tegest Tilahun

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, TEGEST TILAHUN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/12/2024

Date

Subscribed and Sworn to before me this 12 day of June 2024.

Notary Public Signature

KAREN WINTER GONZALEZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 21-8364-01
MY APPT. EXPIRES OCTOBER 22, 2025

(Seal)

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **QHR PHARMACY 1, LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/29/2016, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 06/12/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202406124723114
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site QHR Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03563

Physical Address 765 N. Nellis Blvd #7

City Las Vegas State NV Zip 89110

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-331-6388 Website QHRPharmacyNV.com

Licensing Company Email qhrnellis89110@yahoo.com

Section 2: Personal Information

First LEANDRO Middle LAI HANG Last SETO

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Rancho Bel Air drive

City Las Vegas State NV Zip 89107

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
College OF SOUTHERN NEVADA		04/03/2020-10/30/2022	
Address: 6375 West CHARLESTON Blvd	City: Las Vegas	State: NV	Zip: 89146
Diploma/Degree obtained, if any: GED			

School Name		From - To (MM/YY – MM/YY)	
George Brown College		09/05/13-07/13/15	
Address: 160 Kendal Ave	City: Toronto	State: ON	Zip: M5R1M3
Diploma/Degree obtained, if any: Academic Upgrading			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/10/17-Present	[redacted] Rancho Bel Air drive	Las Vegas	NV	89107
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
ANGELES MEDICAL CENTER			03/20/18 - 04/03/2020
Business Address	**City**	**State**	**Zip**
2123 Civic Center drive	Las Vegas	NV	89030
Phone	**Title**		
702-330-0110	MARKETER		
Description of Duties	Creating Marketing strategies that align with the health providers goals and initiatives.		

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LEANDRO SEDO
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/13/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, LEANDRO SEDO, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/13/24
Date

Subscribed and Sworn to before me this 13th day of June 2024.

Notary Public Signature

ROSA A. SEDO
Notary Public, State of Nevada
Appointment No. 03-83716-1
My Appt. Expires May 28, 2027

(Seal)

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	■ Service Modification*	☐ Nuclear	DEA #: FB7946140
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH PH04343		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Beaker Pharmacy

Physical Address: 7810 Eldorado Pkwy, Ste 200

City: Mckinney State: TX Zip: 75070

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 9729724700 Toll Free # (NAC 639.708, NRS 639.23286): 8663063046

Fax: 4699071197 Contact Email: david@beakerpharmacy.com

Website: www.beakerpharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): David Damaske

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23277

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: David Damaske	NV Pharmacist Registration #: 23277
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): _____

Corporation/Organization Name: Apteek RX

Mailing Address: 7810 Eldorado Pkwy, Ste 200

City: Mckinney State: Tx Zip: 75070

Telephone: 9729724700 Email: david@beakerpharmacy.com

Contact Person Name: David Damaske

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Beaker Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

David Damaske

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

5/22/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Damaske

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

5/22/24

Date

Board Use Only	Date Received: 5/29/24	Amount: $800-cc

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FB7946140	07-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	06-11-2021

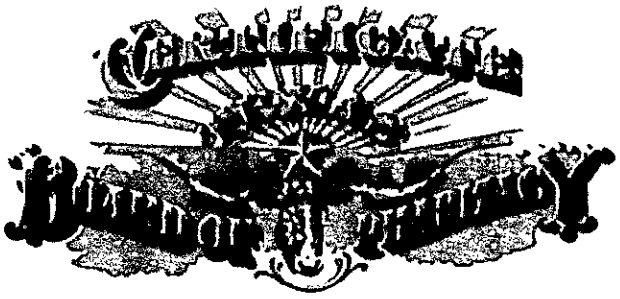
BEAKER PHARMACY
APTEEK RX, LLC
7810 ELDORADO PKWY
STE 200
MCKINNEY, TX 75070-5931

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

1888



This certifies that the pharmacy named below is hereby licensed to operate as a Class **AS** pharmacy.

License No. **32264** Expiration Date: **9/30/2024**

Balances: **7**

BEAKER PHARMACY
7810 ELDORADO PKWY STE 200
MCKINNEY TX 75070



Timothy L. Tucker, Pharm.D.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

1889

TEXAS STATE BOARD OF PHARMACY

Re:	Beaker Pharmacy
Address:	7810 Eldorado Parkway, Suite 200 McKinney, Texas 75070
License No.:	32264
Date Issued:	September 26, 2018
Licensure Status:	Active
Expiration Date:	September 30, 2024
Type of Pharmacy:	Community Sterile Compounding
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Beaker Pharmacy (Texas Pharmacy License #32264) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy

June 7, 2024
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: Beaker Pharmacy TXLic:32264

Address: 7810 Eldorado Pkwy #200

City: Mckinney State: TX Zip: 75070

I hereby authorize the TSBP to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
32264	Active	September 26, 2018	September 30, 2024

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☒ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☒ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☒ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☒ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☐ Yes ☒ No

Signature of State Official	Title	State	Date	State Seal
Lauren D. Briggs	Deputy General Counsel	Texas	June 7, 2024	

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *BEAKER PHARMACY* **License Number:** *32264*

Class of License: *AS*

Inspection Information

Type: *Compliance* **Purpose:** *Licensee Request*

Date: *03/21/2024* **Arrival Time:** *10:15 AM* **Departure Time:** *12:45 PM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Not Applicable*
17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Satisfactory*

Comment

Annual controlled substance inventory completed on 5/3/23

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Satisfactory*
34. Notifications	*Satisfactory*

76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean	*Satisfactory*
04. Balance inspection	*Satisfactory*

Comment

Number of balances: 7
Accuracy of balances is verified by an outside vendor on an annual basis.

05. Equipment Inspection	*Satisfactory*
07. Security	*Satisfactory*
08. Environment	*Satisfactory*
48. Drugs (procurement, temperature, security, out-of-date, samples)	*Satisfactory*
90. TSBP complaint notification	*Satisfactory*

Controlled Substances

10. Prescriptions separated	*Satisfactory*
24. Theft/Loss	*Satisfactory*

Comment

No theft or loss has occurred.

26. Controlled substance prescription compliance	*Satisfactory*
30. Controlled substance invoices dated/initialed by pharmacist	*Satisfactory*
35. Controlled substance invoices separated	*Satisfactory*
46. Drug distribution	*Not Applicable*
53. Possession of controlled substances	*Satisfactory*
57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Satisfactory*
45. Proper dispensing/labeling	*Satisfactory*
54. Proper prepackaging procedures	*Not Applicable*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Satisfactory*
61. Supervision of supportive personnel	*Satisfactory*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Satisfactory*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Satisfactory*
56. Prescription transfers	*Satisfactory*
67. Written drug information provided	*Satisfactory*
80. Patient counseling	*Satisfactory*
82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*
86. Absence of pharmacist records	*Not Applicable*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Satisfactory*
92. Automated dispensing policy & procedures/SOPs	*Not Applicable*

Non-Sterile Compounding

38. Area for non-sterile compounding	*Satisfactory*
43. Records for non-sterile compounding	*Satisfactory*

Compounded Dosage Forms

Allergen extracts	*No*
Parenteral solutions	*Yes*
Parenteral suspensions	*No*
Preservative-free parenterals	*No*
Ophthalmic preparations	*Yes*
Oral or nasal inhalation preparations (not topical spray)	*No*
Bath or soaks for live organs/tissues	*No*

Irrigations for wounds or body cavities	*No*
Any other sterile preparations (implants, pellets, etc) [list]	*No*
Investigational drugs	*No*
Blood products or other biological materials (wound care, autologous, eye drops, etc)	*Yes*
Any compounds using federally controlled substances Schedule I-V (list and percentage)	*Yes*

Comment

Testosterone (about 30% of total dispensed)
Nandrolone (less than 1% of total dispensed)

Does the pharmacy use lyophilizer?	*No*

Environment (Sterile)

S109. Is the cleanroom clean and free of objects that shed particles?	*Satisfactory*
S110. Is the cleanroom used only for sterile preparations?	*Satisfactory*
S119. Does the cleanroom contain only appropriate supplies?	*Satisfactory*
S101. Does the ante-area provide at least ISO Class 8 air quality under dynamic conditions?	*Satisfactory*
S115. Does the ante-area contain a hands-free sink with hot and cold running water?	*Satisfactory*
S102. Does the buffer area provide at least ISO Class 7 air quality under dynamic conditions?	*Satisfactory*
S106. Is the buffer area free from sources of water (e.g., sink, floor drains)?	*Satisfactory*
S108. Is there hands-free access to the buffer area?	*Satisfactory*
S113. Are floors, walls, ceilings & fixtures smooth, impervious and free from cracks & crevices?	*Satisfactory*
S112. Does the floor covering enable regular disinfection?	*Satisfactory*
S118. Are supplies stored above the floor to permit adequate floor cleaning?	*Satisfactory*
S127. Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area and ante-area and between the ante-area and the general environment? Is the pressure differential at least 0.02" wc?	*Satisfactory*
S116. Are temperature and humidity monitored, documented and within the required range?	*Satisfactory*
S167. Is there a thermometer available for the cleanroom and refrigerator(s)?	*Satisfactory*

Primary Engineering Control (PECs) Device

S126. Is the laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02" wc?	*Satisfactory*
S121. Is the PEC able to maintain at least ISO Class 5 conditions while compounding sterile preparations?	*Satisfactory*

S246. Are hazardous drugs prepared in a Class II/III vertical flow BSC or CACI located in an ISO Class 7 area physically separated from other areas?	*Satisfactory*
S247. Does the area where the BSC or CACI is located have not less than 0.01" wc negative pressure adjacent to the positive pressure ISO Class 7 area?	*Satisfactory*
S105. Does the CAI or CACI provide unidirectional airflow?	*Not Applicable*
S104. If the CAI or CACI is used for high-risk sterile compounding, is it placed in an ISO Class 8 area?	*Not Applicable*
S122. If the CAI is not required to be placed in an ISO Class 7 area, does the pharmacy maintain documentation from the manufacturer?	*Not Applicable*
S124. Is the PEC certified by an independent contractor every 6 months and when relocated?	*Satisfactory*
S125. Are prefilters inspected periodically and replaced as needed?	*Satisfactory*
S128. Are differential pressures monitored and documented at least every work shift (at a minimum daily) or by a continuous recording device?	*Satisfactory*

Equipment and Supplies

S174. Does the pharmacy have disposable needles, syringes, and other required or applicable supplies?	*Satisfactory*
S177. Does the pharmacy have lint-free towels or wipes?	*Satisfactory*
S180. Does the pharmacy have masks, caps, gowns with tight cuffs, shoes covers, and beard covers (if applicable)?	*Satisfactory*
S176. Does the pharmacy have handwashing agents with bactericidal action?	*Satisfactory*
S175. Does the pharmacy have disinfectant cleaning solutions and dedicated cleaning supplies?	*Satisfactory*
S179. Does the pharmacy have hazardous spill kits, if applicable?	*Satisfactory*
S171. Does the pharmacy have appropriate containers for needles and syringes?	*Satisfactory*
S170. Does the pharmacy have sterile isopropyl alcohol, sterile gloves, and waterless alcohol-based surgical hand scrub?	*Satisfactory*
S178. Does the pharmacy have appropriate filters and filtration equipment?	*Satisfactory*
S181. If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy, and document at least daily?	*Satisfactory*
S172. Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?	*Satisfactory*

High Risk CSPs

S103. If high-risk CSPs are compounded, does the buffer area provide physical separation from other compounding areas?	*Satisfactory*
S231. Is sterility testing performed if CSPs are prepared in groups > 25, or	*Satisfactory*

S232. If MDVs are prepared for multiple patients or when exposed > 12 hours at 2-8 degrees C before sterilized, or	*Not Applicable*
S233. If exposed > 6 hours at warmer than 8 degrees C before sterilized?	*Not Applicable*
S237. Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk sterile compounding?	*Satisfactory*
S238. Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2-micron filter to remove particulate matter? Is sterilization by filtration performed with a sterile 0.2 – 0.22 micrometer pore size filter within an ISO Class 5 environment or better?	*Satisfactory*
S165. Are filter integrity tests being performed and documented (e.g., bubble point test)?	*Satisfactory*
S239. Are pre-sterilization procedures (weighing and mixing) completed in an ISO Class 8 environment or better?	*Satisfactory*

Sterile Library

S154. Does the pharmacy have a reference on injectable drugs?	*Satisfactory*
S155. Does the pharmacy have a specialty reference?	*Satisfactory*
S156. Does the pharmacy have all of the required (USP chapters 71, 85, 795, 797, 1163) and applicable USP chapters?	*Satisfactory*

Hazardous CSPs

S242. Do personnel wear protective apparel at all times when hazardous drugs are handled?	*Satisfactory*
S243. Do personnel use appropriate safety and containment techniques when preparing hazardous CSPs?	*Satisfactory*
S244. Do personnel dispose of hazardous waste in compliance with local, state, and federal regulations?	*Satisfactory*
S245. Do personnel affix a proper label, including proper precautions inside and outside of the packaging?	*Satisfactory*
S248. Does the pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?	*Satisfactory*
S249. Does the pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment (e.g., closed-system vial transfer device within a BSC)?	*Not Applicable*
S250. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	*Satisfactory*
Does the pharmacy have a plan to comply with USP <800> by the implementation date?	*Yes*
Are hazardous drugs stored separately in compliance with USP <800> (negative pressure at least -0.01" wc to adjacent areas and with at least 12 ACPH)?	*Yes*
Is hazardous drug waste quarantined in a designated area?	*Yes*

Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?	*Yes*

Personnel Cleansing, Garbing, Hand Hygiene

S202. Does hand sanitizing and gowning occur in the ante-area (outside of the buffer area)?	*Satisfactory*
S180. Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclose at the neck? Is the order of garbing appropriate (dirtiest to cleanest)?	*Satisfactory*
S194. Before entering the buffer area, do compounding personnel remove cosmetics?	*Satisfactory*
S195. Before entering the buffer area, do compounding personnel remove all hand, wrist, and other body jewelry/piercings?	*Satisfactory*
S196. Are natural nails kept neat and trim and no wearing of artificial nails or extenders?	*Satisfactory*
S200. Do compounding personnel remove debris from underneath fingernails using a nail cleaner under running warm water?	*Satisfactory*
S192. Are personnel with an apparent illness or open lesions compounding sterile preparations?	*Satisfactory*
S241. When compounding personnel temporarily exit the ISO Class 7 environment, are re-donning procedures properly followed?	*Satisfactory*
S201. Do compounding personnel engage in proper hand hygiene?	*Satisfactory*
S203. Do compounding personnel completely dry hands and forearms using lint-free disposable towels or hand dryer?	*Satisfactory*
S204. Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside the buffer area and prior to donning sterile gloves?	*Satisfactory*
S206. Is sterile isopropyl alcohol applied to gloves throughout the day and when non-sterile surfaces are touched?	*Satisfactory*

Cleaning/Disinfection Procedures

S182. Does the pharmacy have written procedures on the cleaning and disinfecting of the direct and contiguous compounding areas (e.g., beginning of shift, every 30 minutes, before each batch, spills)?	*Satisfactory*
S230. Is cleaning performed by trained personnel using approved agents (described in written SOPs)?	*Satisfactory*
S228. Are supplies & equipment that are removed from shipping cartons wiped with a disinfecting agent (e.g., sterile IPA)?	*Satisfactory*
S226. Are work surfaces and floors in the ante-area and buffer area cleaned and disinfected daily with dedicated supplies?	*Satisfactory*
S227. Are walls, ceilings and shelving in the ante-area and buffer area cleaned and disinfected at least monthly?	*Satisfactory*

S229. Does the pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, name of individual who performed the cleaning)?	*Satisfactory*

Environmental Sampling

S270. Is surface sampling conducted in all ISO classified areas on a periodic basis?	*Satisfactory*
S272. Is viable air sampling performed?	*Satisfactory*
S273. Is viable air sampling documented by properly trained individuals for all risk levels every 6 months?	*Satisfactory*
S271. Are environmental sampling results evaluated and addressed (i.e., action levels followed)?	*Satisfactory*

Records of CSPs

S252. Does the pharmacy maintain records relating to CSPs for a minimum of 2 years?	*Satisfactory*
S253. Do compounding records include the date and time of preparation of a CSP?	*Satisfactory*
S254. Do compounding records include the complete formula of a CSP?	*Satisfactory*
S257. Do compounding records include the quantities of materials used in a CSP?	*Satisfactory*
S255. Do compounding records include the signature or initials of who prepared a CSP?	*Satisfactory*
S256. Do compounding records include the signature or initials of who conducted the final check of a CSP?	*Satisfactory*
S258. Do compounding records include the container used and the number of units prepared for a CSP?	*Satisfactory*
S259. Do compounding records include the criteria used to determine the beyond-use date of a CSP?	*Satisfactory*
S260. Do compounding records include the documentation of performance of quality control procedures?	*Satisfactory*
S261. Are master worksheets and preparation worksheets for batch compounding complete?	*Satisfactory*
S262. Are master worksheets developed and approved by a pharmacist?	*Satisfactory*

General Operational Requirements

S166. Is a pharmacist available at all times (24/7)?	*Satisfactory*
S187. Are written SOPs developed and implemented for all significant procedures in the compounding area to include at a minimum: the facility, equipment, personnel, preparation evaluation, quality assurance, preparation recall, packaging, and storage of CSPs?	*Satisfactory*
S188. Does the pharmacy have all required written policies (e.g., pharmaceutical care services, sampling plan, recalls)?	*Satisfactory*
S158. If the pharmacy compounds commercially available products, does the pharmacy document the need by verifying and monitoring a drug shortage list (including if the preparation is quarantined/not available once removed from the shortage list)? Or,	*Satisfactory*

S158. Does the pharmacy document the need for compounding commercially available products by individual patient needs determined by the prescribing practitioner (i.e, hypersensitivity to inactive ingredients or alternate dosage form)?	*Not Applicable*
S275. If the pharmacy dispenses prescriptions to patients in other states, does the pharmacy have proper licensure in those states?	*Satisfactory*

Office Use Compounding & Distribution of CSPs

S163. Does the pharmacy have a written agreement with the prescriber that meets all requirements to distribute compounded sterile preparations to practitioners for office use?	*Not Applicable*
S162. If the pharmacy is distributing CSPs to another pharmacy, does the pharmacy meet the requirements for such distribution?	*Not Applicable*
Is the pharmacy registered with the FDA as an Outsourcing Facility (503B)?	*No*

Quality Control & Verification of Compounding Accuracy

S207. Does a pharmacist review all compounding records for accuracy and perform the final check of a CSP?	*Satisfactory*
S185. Are periodic in-process checks for CSPs defined in written procedures and conducted as defined?	*Satisfactory*
S191. Are all drug components USP/NF grade substances manufactured in an FDA-registered facility? If USP/NF grade substances are not available, are the drug components of chemical grade in CP, AR, ACS, or Food Chemical Codex categories?	*Satisfactory*
S191. Is a Certificate of Analysis available for all components of the preparation if materials are not purchased through an FDA-registered facility?	*Satisfactory*
S191. Are any CSPs prepared by the pharmacy listed on the federal FDA list of drug products that are withdrawn or removed from the market for safety reasons?	*Satisfactory*

Veterinary Compounding

Are APIs or other components labeled for veterinary use segregated or marked to prevent use for human compounding?	*Not Applicable*
Does the pharmacy meet the same standards for animal compounding as human compounding?	*Not Applicable*
Is the pharmacist knowledgeable or does the pharmacy have up-to-date references regarding species limits that can result in toxicity when compounding with particular drugs/excipients?	*Not Applicable*
Does the pharmacy document if the animal is a pet or used for food?	*Not Applicable*
Is the pharmacist familiar with, or does the pharmacy have the most up-to date references regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals?	*Not Applicable*
Does the pharmacy have a list of drugs and components that have been designated by state or federal authorities as prohibited ingredients in CSPs for food-producing animals?	*Not Applicable*
Is the pharmacist familiar with, or does the pharmacy have the most up-to-date reference regarding regulations for drug use in performance animals?	*Not Applicable*

Label

S209. Is the CSP properly labeled to include the generic name(s), and	*Satisfactory*
S210. For outpatient prescriptions, does the label include a statement that the CSP has been compounded by the pharmacy?	*Satisfactory*
S211. Does the label include a beyond-use date?	*Satisfactory*
S213. If the CSP is compounded as a batch, does the label contain a unique lot number assigned to the batch, and	*Satisfactory*
S214. Quantity, and	*Satisfactory*
S215. Appropriate ancillary instructions, such as storage or cautionary statements, and	*Satisfactory*
S216. Any device-specific instructions, if appropriate?	*Satisfactory*
S220. Are CSPs assigned a beyond-use date based on the specified labeling for the drug, appropriate literature sources, or direct testing?	*Satisfactory*

Training & Competency Testing

S129. Has each pharmacist completed the required education and training prior to engaging in sterile compounding?	*Satisfactory*
S130. Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?	*Satisfactory*
S142. Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation/testing (e.g., media-fill testing, gloved fingertip/thumb testing)? Does the pharmacy have an on-the-job training program?	*Satisfactory*
S144. Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel (e.g., observation of aseptic technique, media-fill testing, gloved fingertip/thumb testing, continuing education)?	*Satisfactory*

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).

David Damaske PIC #32264

Terri Burrows

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Beaker Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): PH04343

Physical Address: 7810 Eldorado Pkwy, Ste 200

City: Mckinney State: TX Zip: 75070

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 866-306-3046 Toll Free # (NAC 639.708, NRS 639.23286): 866-306-3046

Fax: 469-907-1197 Contact Email: david@beakerpharmacy.com

Website: www.beakerpharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): David Damaske

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23277

Name of Person with direct knowledge of compounding procedures: David Damaske/ Sheila Cline

Email of Person with direct knowledge of compounding procedures: David Damaske/ Sheila Cline

Telephone of Person with direct knowledge of compounding procedures: 866-306-3046

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☒ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
That we know of potentially: Vitamin B12, hormones, eye drops, glutathione, trimix

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
Every product has testing has to validate the BUD we assign. Every interval is checked and validated (30d, 60d, 90d depending on the product).

6. What laboratory performs this additional testing?

Name: ARL BioPharma

Address: 840 Research Parkway #546

City: OKC State: OK Zip: 73104

Telephone: 405-271-1144

7. What is your procedure for visual inspection of compounded sterile products?
Technicians: black/white background board is used, level line is checked. Cracks, imperfections and seal/crimped checked.
Pharmacists: Consistent volume, labels, look of the solution, seals and crimp checked.

8. How often do you perform glove fingertip and medial fill testing?
During training and currently every 6 months. We are moving to every 3 months in summer

9. What is your policy if an employee fails a glove fingertip or media-fill test?
Retrain and retest

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Techs: training signoff document, skills assessment, glove tip, media fills, batch size media fill. We send technicians through an accredited 40 hr sterile class if they don't have it prior to joining us.
Pharmacists: We send them through an accredited 40 hour sterile class if they don't have it prior to joining us. We also do a skills assessment, glove tip and media fill tests.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Cleaning agents: TB1 3300, Peridox RTU, Sterile IPA

Hoods: clean begining of shift, end of shift, between batches, if a spill occurs
Walls, carts, ceiling: cleaned monthly starting high to low (ceiling to floor)
Sink, pushbuttons, high touch surfaces and passthrough cleaned daily

12. Who performs the sterile compounding process at your facility?
Properly trained technicians

13. Who is responsible and accountable for the sterile compounding process at your facility?
David Damaske (PIC) and Sheila Cline (compounding lead)

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Cold ship overnight if temperature sensitive. During summers every item is sent with ice packs even if refrigeration not required. Tests are done yearly to validate.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding:)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☑ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☑ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☑ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☑ No
7. If yes, list the name of the device:		

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?
Patient information sheet provides any details regarding the drug, storage and disposal.

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
Techs: training signoff document, skills assessment, glove tip, media fills, batch size media fill. We send technicians through an accredited 40 hr sterile class if they don't have it prior to joining us.
Pharmacists: We send them through an accredited 40 hour sterile class if they don't have it prior to joining us. We also do a skills assessment, glove tip and media fill tests.

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
Hormones, eye drops, trimix,

2. What sterilization methods are utilized at your facility?
Filtration

3. Does your facility utilize biological indicators? ■ Yes ☐ No

4. If yes, describe how they are utilized:
Autoclave and oven for spinners and beakers

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Damaske
Name of Person who Completed the Form

President
Title

Signature (copies or stamps not accepted)

3/26/24
Date

Board Use Only	Date Received: 4/2/24 Date Approved: _____ Approved By: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Beaker Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH04343

Physical Address 7810 Eldorado Pkwy, Ste 200

City Mckinney State TX Zip 75070

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 9729724700 Website www.beakerpharmacy.com

Licensing Company Email david@beakerpharmacy.com

Section 2: Personal Information

First David Middle _____ Last Damaske

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addres[redacted]errville Dr

City Allen State TX Zip 75013

Telephone [redacted] Email david@beakerpharmacy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Memphis		5/14-5/18	
Address	City	State	Zip
3720 Alumni Ave	Memphis	TN	38152
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Midwestern University-Glendale		8/98-5/01	
Address	City	State	Zip
19555 N 59th Ave	Glendale	AZ	85308
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Grand Canyon University		8/96-5/98	
Address	City	State	Zip
3300 W Cambelback Rd	Phoenix	AZ	85017
Diploma/Degree obtained, if any			
Pharm pre-requisites			

School Name		From - To (MM/YY – MM/YY)	
Apollo HS		92-96	
Address	City	State	Zip
8045 N 47th Ave	Glendale	AZ	85302
Diploma/Degree obtained, if any			
HS dipoloma			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
3/07-present	[redacted] Kerrville Dr	Allen	TX	75013
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Beaker Pharmacy			11/18-present	
Business Address		**City**	**State**	**Zip**
7810 Eldorado Pkwy, Ste 200		Mckinney	TX	75070
Phone	**Title**		**Number of Employed Hours**	
9729724700	Owner/PIC		11000+	
Description of Duties				
Day to day staffing and operations				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, David Damaske, **certify that as the designated representative for**

Beaker Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Damaske

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/22/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Damaske

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/22/24

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, David Damaske, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/22/24

Date

Subscribed and Sworn to before me this 22 day of May.

Notary Public Signature

(Seal)

Franchise Tax Account Status

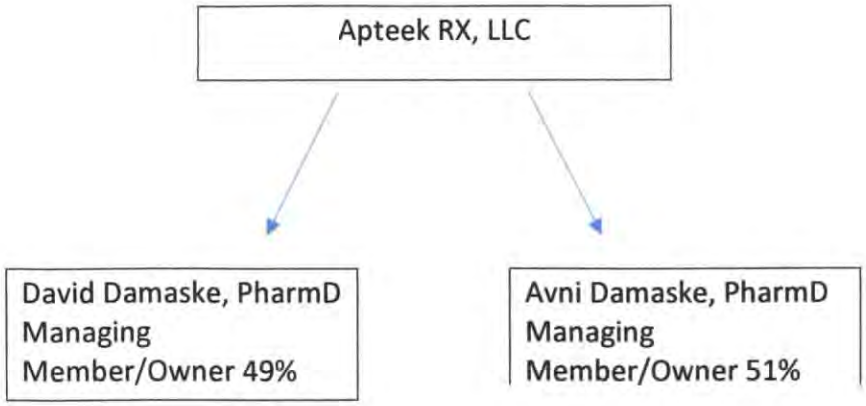
As of : 05/22/2024 20:24:35

This page is valid for most business transactions but is not sufficient for filings with the Secretary of State

APTEEK RX, LLC	
Texas Taxpayer Number	32066296156
Mailing Address	1308 KERRVILLE DR ALLEN, TX 75013-5350
Right to Transact Business in Texas	ACTIVE
State of Formation	TX
Effective SOS Registration Date	02/19/2018
Texas SOS File Number	0802939846
Registered Agent Name	DAVID DAMASKE
Registered Office Street Address	1308 KERRVILLE DR ALLEN, TX 75013

Apteek RX, LLC Organizational Chart
Created April 2018

*Note—Owners are married



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Beaker Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04343

Physical Address: 7810 Eldorado Pkwy, Ste 200

City: Mckinney State: TX Zip: 75070

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 9729724700 Website: www.beakerpharmacy.com

Licensing Company Email: david@beakerpharmacy.com

Section 2: Personal Information

First: David Middle: Last: Damaske

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Kerrville Dr

City: Allen State: TX Zip: 75013

Telephone: [redacted] Email: david@beakerpharmacy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Univeristy of Memphis		5/14-5/18	
Address	**City**	**State**	**Zip**
3720 Alumni Ave	Memphis	TN	38152
Diploma/Degree obtained, if any			
MBA			
School Name		**From - To (MM/YY – MM/YY)**	
Midwestern University-Glendale		08/98-5/01	
Address	**City**	**State**	**Zip**
19555 N 59th Ave	Glendale	AZ	85308
Diploma/Degree obtained, if any			
PharmD			
School Name		**From - To (MM/YY – MM/YY)**	
Grand Canyon University		8/96-5/98	
Address	**City**	**State**	**Zip**
3300 W Camelback Rd	Phoenix	AZ	85017
Diploma/Degree obtained, if any			
Pharmacy pre-requisites			
School Name		**From - To (MM/YY – MM/YY)**	
Apollo HS		92-96	
Address	**City**	**State**	**Zip**
8045 N 47th Ave	Glendale	AZ	85302
Diploma/Degree obtained, if any			
High School			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/07-present	[redacted]erville Dr	Allen	TX	75013
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Beaker Pharmacy			11/18-present
Business Address	**City**	**State**	**Zip**
7810 Eldorado Pkwy Ste 200	Mckinney	TX	75070
Phone	**Title**		
9729724700	Owner/PIC		
Description of Duties			
Day to day operations			

Business Name			From - To (MM/YY – MM/YY)
Texas Health HEB Hospital			3/11-6/18
Business Address	**City**	**State**	**Zip**
1600 Hospital Pkwy	Bedford	TX	76022
Phone	**Title**		
8178484000	Director of Pharmacy		
Description of Duties			
Day to day operations of the hospital pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Damaske

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/22/24

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, David Damaske, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/22/24

Date

Subscribed and Sworn to before me this 22 day of May.

Notary Public Signature

Harendra Patel
NOTARY PUBLIC - STATE OF TEXAS
ID# 134216212
COMM. EXP. 02-23-2027
[Seal]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Beaker Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04343

Physical Address 7810 Eldorado Pkwy, Ste 200

City Mckinney State TX Zip 75070

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 9729724700 Website www.beakerpharmacy.com

Licensing Company Email david@beakerpharmacy.com

Section 2: Personal Information

First Avani Middle _____ Last Damaske

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Kerrville Dr

City Allen State TX Zip 75013

Telephone [redacted] Email avni@beakerpharmacy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University-Glendale		8/98-5/01	
Address	**City**	**State**	**Zip**
19555 N 59th Ave	Glendale	AZ	85308
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of North Texas		8/93-5/98	
Address	**City**	**State**	**Zip**
2204 Prairie St	Denton	TX	76201
Diploma/Degree obtained, if any			
Biology			

School Name		From - To (MM/YY – MM/YY)	
Plano Sr High		89-93	
Address	**City**	**State**	**Zip**
2200 Independence Pkwy	Plano	TX	75075
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/07-present	[redacted] Kerrville Dr	Allen	TX	75013

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Beaker Pharmacy			2/24-present
Business Address	**City**	**State**	**Zip**
7810 Eldorado Pkwy Ste 200	Mckinney	TX	75070
Phone	**Title**		
9729724700	Owner/pharmacist		
Description of Duties			
Day to day operations			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Avani Damaske

Print Name (First, Last)

aDamke

Original Signature (electronic, copies or stamps not accepted)

5/22/24

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, Avani Damaske, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

aDamke

Original Signature

5/22/24

Date

Subscribed and Sworn to before me this 22 day of May.

H Patel

Notary Public Signature

Harendra Patel
NOTARY PUBLIC - STATE OF TEXAS
ID# 134216212
COMM. EXP. 02-23-2027
(Seal)

4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☒ Service Modification* ☒ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 01797	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Closed Door	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Option Care

Physical Address: 2233 S Presidents Drive, Suite B

City: Salt Lake City State: UT Zip: 84120

Mailing Address (if different from physical address): 3000 Lakeside Dr, Suite 300N

City: Bannockburn State: IL Zip: 60015

Telephone: (866)978-9600 Toll Free # (NAC 639.708, NRS 639.23286): (866) 978-9600

Fax: (801) 978-0020 Contact Email: oc-peandle@optioncare.com

Website: optioncare.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Cynthia Smith

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23338

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Cynthia Smith	NV Pharmacist Registration #: 233338
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Option Care Enterprises, Inc.

Corporation/Organization Name: Critical Care Systems, LLC

Mailing Address: 3000 Lakeside Dr., Suite 300N

City: Bannockburn State: IL Zip: 60015

Telephone: 312-940-2528 Email: oc-peandl@optioncare.com

Contact Person Name: Michelle Mazzenga

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager (title) for Option Care (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Collin Smyser

Print Name of Authorized Person

Collin Smyser

Original signature of Authorized Person (copies or stamps not accepted)

12/15/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Collin Smyser

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/15/23

Date

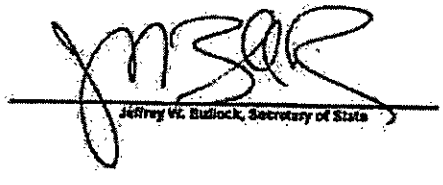
Board Use Only	Date Received: 3/28/24	Amount: $500 - check 9009017

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CRITICAL CARE SYSTEMS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF MARCH, A.D. 2024.





2256955 8300

5R# 20240848466

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202940615

Date: 03-04-24

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing

160 E 300 S
P.O. Box 16741
Salt Lake City, UT 84114-6741
Email: DOPLInvestigations@utah.gov
Telephone : (801) 530-6628
Toll Free in Utah: (866) 275-3675
Investigation Fax: (801) 530-6301
Website: www.dopl.utah.gov

CLASS B
CLOSED DOOR
INSPECTION

☐ Random
☑ Opening

INFORMATION

Pharmacy Name: Critical Care Systems, Inc. dba: Option Care Utah Date: 12/5/2019

License Number: 11397776-1704 Exp Date: 12/21/2019

C.S. License Number: 11397776-8913 Exp Date: 12/21/2019

DEA Registration: FC8771443 Exp Date: 12/31/2021

Pharmacy FEIN # 04-3115329

Pharmacy Email: alesia.hanson@optioncare.com, oc-peandi@optioncare.com

Pharmacy Phone # 801-978-9600 Fax: 801-880-4799

Toll Free Number: 866-978-9600

Affiliated Websites:

Pharmacy Hours: Monday-Friday: 9-5 Saturday: on call Sunday: on call

Pharmacy Address: 2233 S Presidents Dr. Suite B

City: Salt Lake City State: Ut Zip: 84120

Pharmacist In Charge (PIC): Alesia Lynne Hanson

PIC License # 287187-1701 Expiration Date: 9/30/2021

Personnel

List ALL pharmacists, interns, pharmacy technicians and techs-in-training (attach a separate sheet, if necessary):

Name:	License #	Exp:
(see attached)		

Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:

INSPECTION

	YES	NO	
1	☑	☐	Class B pharmacy means a pharmacy located in Utah that is authorized to provide pharmaceutical care for patients in an institutional setting; and whose primary purpose is to provide a physical environment for patients to obtain health care services; and includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and pharmaceutical administration and sterile product preparation facilities. [UCA 58-17b-102 (11)(a)(i-ii)(b)(i-ii)]
2	☑	☐	The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable. The list may be maintained in paper or electronic form. [UAC R156-17b-614a (5)]
3	☑	☐	Notification has been provided to the Division in regards to the unique email address used in self audits or alerts for the pharmacy. The pharmacy will notify the Division of any change in the email address within seven days of the change. [UAC R156-17b-603(3)(t) (i-ii)]
4	☑	☐	Notification has been provided to the Division in regards to the assignment of the PIC at the above stated pharmacy. The Division is notified of a change in PIC within 30 days of the change. [UAC R156-17b-603 (3) (s)]
5	☐	☐	If the facility has a pharmacy technician training program, the program and curriculum of education and training, meets standards established by Division rule made in collaboration with the Board. [UAC R156-17b-303a (3)] ☑ N/A
6	☑	☐	No more than one pharmacy technician trainee per shift shall practice in a pharmacy. A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist. [UAC R156-17b-601(5)]
7	☑	☐	Pharmacy technicians shall have general supervision by a pharmacist. [UAC R156-17b-601(4)]
8	☑	☐	The operating standards for a Pharmacist acting as a preceptor includes meeting the following criteria by providing direct, on-site supervision to no more than two pharmacy interns during a working shift. [UAC R156-17b-606(1)(d)(i)]
9	☑	☐	The pharmacist-in-charge (PIC) is responsible for assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to pharmacy personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare. [UAC R156-17b-603 (3) (r)]
10	☑	☐	All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility does wear on their person a clearly visible and readable identification showing the individual's name and position. [UCA 58-17b-603 (1)]
11	☑	☐	When communicating by any means, written, verbal, or electronic, pharmacy personnel do identify themselves as to licensure classification. [UCA 58-17b-603 (2)]

12 ☑ ☐ The facility or parent company does maintain a record for not less than five years of the initials or identification codes that identify each dispensing pharmacist by name. The initials or identification codes shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used. [UAC R156-17b-614a (9)]

13 ☑ ☐ The facility does have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:

- ☑ UCA 58-1 (DOPL Licensing Act)
- ☑ UAC R156-1 (General Rules of DOPL)
- ☑ UCA 58-17b (Pharmacy Practice Act)
- ☑ UAC R156-17b(Pharmacy Practice Act Rules)
- ☑ UCA 58-37 (Controlled Substance Act)
- ☑ UAC R156-37(Controlled Substance Act Rules)
- ☑ UCA 58-37f (Controlled Substance Database Act)
- ☑ UAC R156-37f (Controlled Substance Database Act Rule)
- ☑ Code of Federal Regulations
- ☑ FDA Approved Drug Product(Orange Book)
- ☑ General Drug References

[UAC R156-17b-614a (4) (a-k)]

14 ☑ ☐ The facility is well lighted, ventilated, clean and sanitary. [UAC R156-17b-614a (1) (a)]

15 ☑ ☐ If transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, shall have a sink with hot and cold culinary water separate and apart from restroom facilities. [UAC R156-17b-614a (b)]

16 ☑ ☐ The facility is equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. [UAC R156-17b-614a (1) (c)]

17 ☑ ☐ The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility. [UAC R156-17b-614a (1) (d)]

18 ☑ ☐ All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label. [UAC R156-17b-605 (1)]

19 ☑ ☐ The facility is stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare. [UAC R156-17b-614a (1) (e)]

20 ☑ ☐ If dispensing controlled substances, the facility is equipped with a security system to permit detection of entry at all times when the facility is closed, and provide notice of unauthorized entry to an individual, and be equipped with a lock on any entrances to the facility where drugs are stored. [UAC R156-17b-614a (1) (f)(i-ii)(g)]

21 ☑ ☐ If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy. [UAC R156-17b-614a (16)] ☐ N/A

22 ☑ ☐ Only a licensed Utah pharmacist or authorized pharmacy personnel does have access to the pharmacy when the pharmacy is closed. [UAC R156-17b-614a (8)]

23 ☑ ☐ A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist is physically present and immediately available in the facility. [UAC R156-17b-614a(7)]

24 ☑ ☐ The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (2)]

25 ☑ ☐ The temperature of the refrigerator and freezer is maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain the log entry for three years. [UAC R156-17b-614a (2)]

26 ☑ ☐ For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as: [UAC R156-17b-611 (2) (a-g)]

- ☑ Inappropriate drug utilization
- ☑ Drug-disease contraindications
- ☑ Incorrect drug dosage
- ☑ Drug-allergy interactions
- ☑ Therapeutic duplications
- ☑ Drug-drug interactions
- ☑ Incorrect duration of drug treatment
- ☑ Clinical abuse or misuse

27 ☑ ☐ Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the patient's drugs. [R156-17b-610 (7)]

28 ☑ ☐ Every pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed. If the patient's agent delivers the prescription in person to the pharmacist or pharmacy intern; or receives the drug in person at the time it is dispensed at the facility. [UCA 58-17b-613 (1)]

29 ☑ ☐ A pharmacist or pharmacy intern that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery shall provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses and provide each patient with a toll-free telephone number by which the patient can contact the pharmacist or pharmacy intern at the pharmacy for counseling. [UCA 58-17b-613(2)]

30 ☑ ☐ If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable: [UCA R156-17b-610(6)(a-c)

☑ the pharmacy shall provide the information specified in R156-17b-610(3) be delivered with the dispensed prescription in writing:

- ☑ (a) the name and description of the prescription drug;
- ☑ (b) the dosage form, dose, route of administration and duration of drug therapy;
- ☑ (c) intended use of the drug, when known, and expected action;
- ☑ (d) special directions and precautions for preparation, administration and use by the patient;
- ☑ (e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- ☑ (f) techniques for self-monitoring drug therapy;
- ☑ (g) proper storage;
- ☑ (h) prescription refill information;
- ☑ (i) action to be taken in the event of a missed dose;
- ☑ (j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and
- ☑ (k) the date after which the prescription should not be taken or used, or the beyond use date.

☑ if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions.." |UAC R156-17b- 610-(6)(b)|

☑ written information provided in Subsection (b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information

31 ☑ ☐ Counseling shall be offered orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits oral communication [UAC R156-17b-610(1)]

32 ☑ ☐ A pharmacy facility shall orally offer to counsel but shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses counseling. [UAC R156-17b-610(2)]

33 ☑ ☐ The offer to counsel is documented and said documentation shall be available to the Division. These records must he maintained for a period of five years and be available for inspection within 7-10 business days. [UAC R156-17b-610 (4)]

34 ☑ ☐ A pharmacy may only deliver a prescription drug to a patient or a patient's agent in person at the pharmacy or via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is delivered to the patient or patient's agent or return to the pharmacy. [UCA 58-17b-602 (9)(a)(b)(i-ii)]

35 ☑ ☐ A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, or other responsible employee:

☑ Use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packing material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication.

☑ Use shipping containers that are sealed in a manner to detect evidence of opening or tampering.

☑ Develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drug.

☑ Provide for an electronic, telephonic, or written communication mechanism for a pharmacy to offer counseling to the patient as defined in section 58-17b-613; and provide documentation of such counseling.

☑ Provide information to the patient indicating what the patient should do if the integrity of the package or drug was compromised during shipment. [UAC R156-17b-608]

36 ☑ ☐ Each drug dispensed from the pharmacy does have a label securely affixed to the container indicating the required minimum information, including: [UCA 58-17b-602 (5) (a-h)]

☑ name, address, & phone number of pharmacy
☑ serial number of prescription
☑ filling date or last dispensing date
☑ name of the patient or animal owner/species

☑ name of the prescriber
☑ trade, generic or chemical name
(Unless Otherwise Indicated by Prescriber)

☑ directions for use & cautionary statements
☑ amount dispensed & strength of dosage form
☑ beyond use date

37 ☑ ☐ Unless otherwise requested, child-resistant containers will be used for dispensing medications to patients. [UAC 58-1-502(6)& 16 CFR 1700.14]

38 ☑ ☐ Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.21]

39 ☑ ☐ The registered pharmacy does only processes electronically signed prescriptions for controlled substances under the following conditions: the pharmacy uses a pharmacy application that meets all the applicable requirements; the prescription is otherwise in conformity with the requirements of the Code of Federal Regulations; and Certification Authority (CA) has been obtained. The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form *(i.e. facsimile)* for transmission. [UAC R156-17b-613(1) & CFR, Title 21, Chapter 11, Section 1311]

40 ☑ ☐ Prescription files, including refill information, are maintained for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612.(4)]

41 ☑ ☐ Prescription records may be maintained electronically so long as the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains all of the information required by federal and state law; and an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders. [UAC R156-37-602 (4) (a-b)]

42 ☑ ☐ All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3, 5)]

43 ☑ ☐ All records relating to Schedule III, IV, V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3, 6)]

44 ☑ ☐ Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems. [UAC R156-17b-605 (4)]

45 ☑ ☐ General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605 (2)(a)(b)(c)(e)(f)(i)]

- ☑ the PIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;
- ☑ the inventory records shall be maintained for a period of five years and be readily available for inspection
- ☑ the inventory shall be filed separately from all records
- ☑ the inventory may be taken either as the opening of the business or the close of business on the inventory date;
- ☑ the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory.

☑ if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

46 ☑ ☐ All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances. [UAC R156-17b-605(7)]

47 ☑ ☐ The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(5)]

48 ☑ ☐ Any facility who experiences a shortage or theft of controlled substances does immediately notify law enforcement and file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau. [UAC R156-37-602 (2)]

49 ☑ ☐ Pharmacists or other responsible individuals do verify that the suppliers' invoices of controlled substances, listed on the invoices were actually received by clearly recording their initials and the actual date of receipt of the controlled substances. [UAC R156-17b-614a (12)]

50 ☑ ☐ The facility does maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (13)]

51 ☑ ☐ The facility does maintain a copy 3 of DEA order form (form 222) which has been properly dated, initialed, and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b614a (10)]

52 ☑ ☐ The Division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information: real-time submission of the information required to be submitted under this part of the controlled substance database; and 24-hour dail or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. [UCA 58-37f-203(1)(a)(i,ii)]

53 ☑ ☐ The PIC does for each controlled substance dispensed by a pharmacist under the PIC's supervision,..submit to the division ...positive identification of the individual receiving the prescription, including the type of identification and any identifying numbers on the identification. [UCA 58-37f-203 (3) (c)]

54 ☐ ☑ The pharmacy maintains emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMT's, ambulances)? If the answer is "yes", note name(s) of facilities or entities.

55 ☐ ☑ The pharmacy maintains automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home? If the answer is "yes", note type and location.

56 ☐ ☑ The pharmacy utilizes an Automated Pharmacy System? If the answer is "yes" to this question, a automation questionnaire must be completed. [UAC R156-17b-620]

57 ☐ ☑ Does the pharmacy purchase any compound products from other entities for dispensing to patients? [UAC 58-17b-102(18)(b)(i)]

58 ☐ ☑ The facility is engaged in medium or complex compounding activities as defined by USP 35 Chapter 795. If you answer "yes" to this question, a compounding questionnaire must be completed. [(UAC R156-17b-614a (3)]

59 ☑ ☐ The facility is engaged in low, medium, or high risk *sterile* compounding as defined by USP 35 Chapter 797. If you answer "yes" to this question, a compounding questionnaire must be completed. [UAC R156-17b-614a (3)]

COMMENTS

1. Facility had a change of ownership that occurred on 8/6/2019.

2. Date of new inventory was conducted on 8/31/2019. CS inventories were conducted on 8/7/2019.

3. The facility is participating in sterile compounding. A sterile compounding inspection was conducted.

OBSERVATION

1. Facility is compounding sterile product for Encompass Health. They will verify how billing is being performed for the compounds. If there is a sale between Encompass Health and Option Care, Option care will work with Encompass Health so that a sale between the facilities is not occurring. Option care will report to the Division the process, and solution.

☑ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: [signature] Date: 12-5-19

Name of Responsible Party (Print): Alesa Hanson

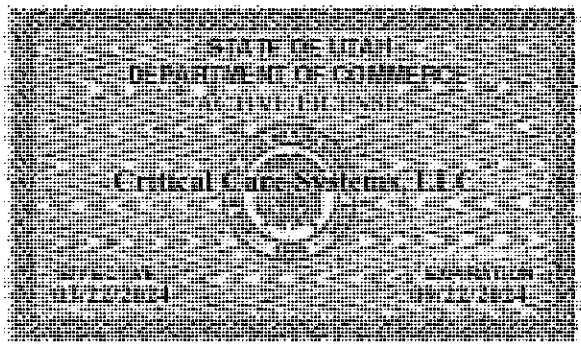
Signature of Division Investigator: [signature] Date: 12/5/19

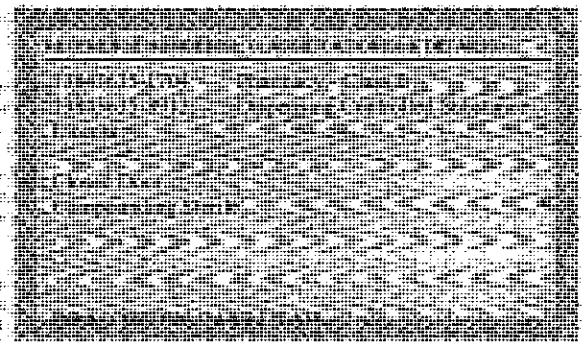
Name of Division Investigator (Print): Shandee McIntyre

Revised 6/2016

OFFICERS AND DIRECTORS
CRITICAL CARE SYSTEM, LLC (DE)

TITLE	NAME	CORPORATE ADDRESS
Manager	Michael Shapiro	3000 Lakeside Drive Suite 300N Bannockburn, IL 60015
Manager	Collin Smyser	3000 Lakeside Drive Suite 300N Bannockburn, IL 60015



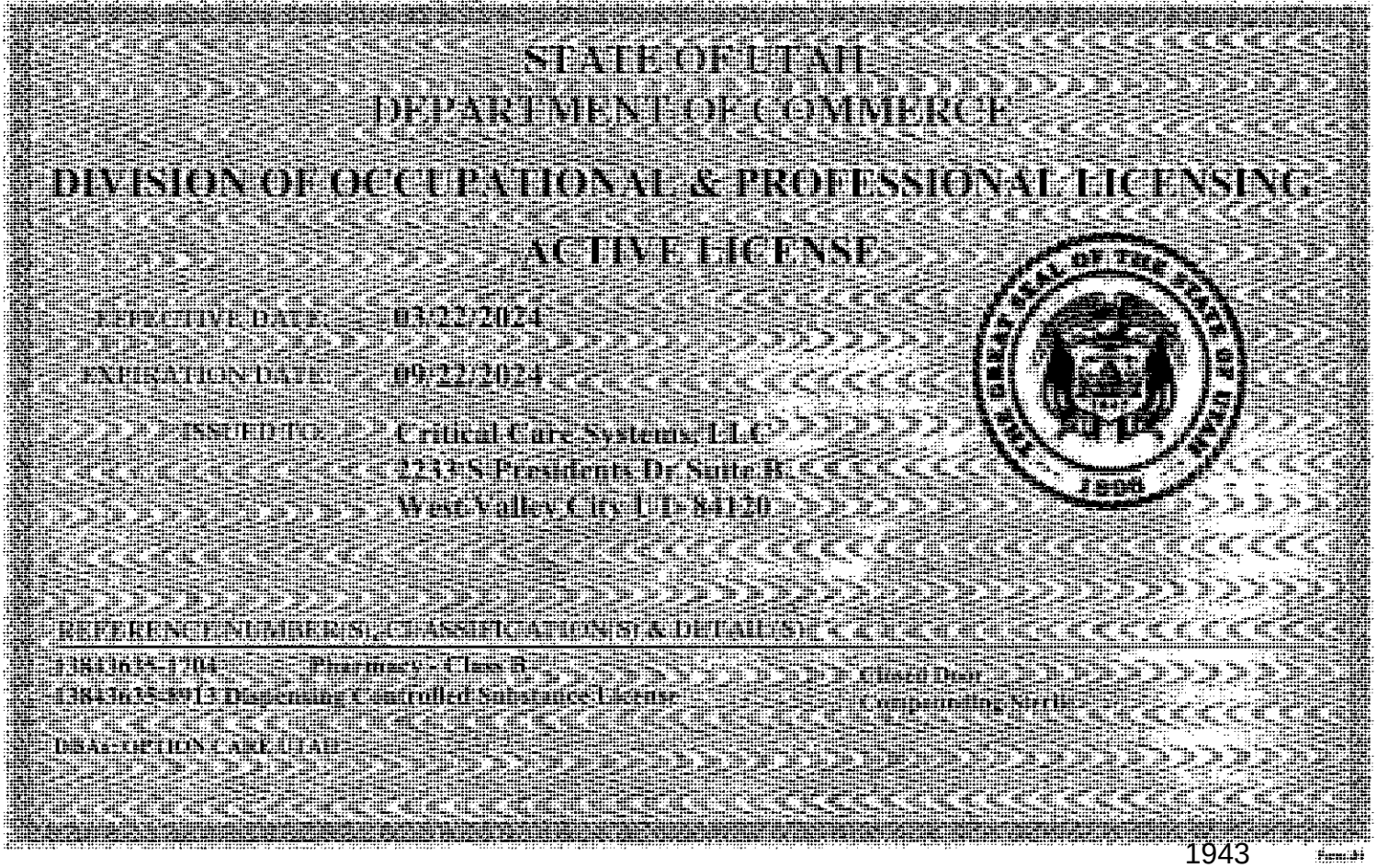


IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

CRITICAL CARE SYSTEMS, LLC
2233 S PRESIDENTS DR SUITE B
WEST VALLEY CITY UT 84120

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.



Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CRITICAL CARE SYSTEMS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF MARCH, A.D. 2024.





2256955 8300

SR# 20240848466

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202940615

Date: 03-04-24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Critical Care Systems, LLC d/b/a Option Care Utah

Pharmacy/Wholesaler License # (if applicable): PH01797

Physical Address: 2233 S. Presidents Drive, Suite B

City: Salt Lake City State: UT Zip: 84120

Mailing Address (if different from physical address): 3000 Lakeside Dr., Suite 300N

City: Bannockburn State: IL Zip: 60015

Telephone: (866) 978-9600 Website: optioncare.com

Licensing Company Email: oc-peandl@optioncare.com

Section 2: Personal Information

First: Cynthia Middle: Last: Smith

Alias(es, nicknames, name changes, etc.): Cindy Redd

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] S. Presidents Drive, Suite B

City: Salt Lake City State: UT Zip: 84120

Telephone: [redacted] Email: cynthia.smith@optioncare.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
Roseman College of Pharmacy	10894 River Front Pkwy	South Jordan	UT	84095	08/15 - 08/18	Pharm D
Weberstate University	3848 Harrison Blvd	Ogden	UT	84408	01/12 - 05/15	
Antelope Valley College	3041 W AVE K	Lancaster	CA	93536	09/84 - 05/86	
Antelope Valley High School	44900 Division St	Lancaster	CA	93535	08/79 - 06/83	High School Diploma
					From - To (MM/YY – MM/YY	

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/19 - 05/24	[redacted] W 625 N	West Point	UT	84015
05/19 - 08/19	[redacted] E 2825 N	Layton	UT	84040
10/18 - 05/19	[redacted] Constelation Dr	Livingston	MT	59047
06/06 - 10/18	[redacted] 2200 N	Layton	UT	84041
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Option Care			From - To (MM/YY – MM/YY): 1/21 – 05/24
Business Address: 2233 S Presidents Dr, Suite B	City: West Valley	State: UT	Zip: 84120
Phone: 801-978-9600	Title: Clinical Pharmacist		Number of Employed Hours: 5160
Description of Duties: Processing Sterile compounds and IV therapy Orders, patient counseling. cleanroom certification			
Business Name: CVS Pharmacy			From - To (MM/YY – MM/YY): 5/19 – 11/20
Business Address: 1982 W 1700 S	City: Syracuse	State: UT	Zip: 84075
Phone: 801-825-2679	Title: Pharmacy Manager		Number of Employed Hours: 2880
Description of Duties: Managed inventory. Customer complaints, supervised 5-10 employees, including other Pharmacist. Controlled and reported intake/sales of Controlled substances.			
Business Name: Shopko Pharmacy			From - To (MM/YY – MM/YY): 9/18 to 1/19
Business Address: 100 Washington St	City: Livingston	State: MT	Zip: 59047
Phone: 406-222-1188	Title: Pharmacy Manager		Number of Employed Hours: 640
Description of Duties: Managed inventory, Customer sales and complaints. Supervised 3-6 employees including technicians/pharmacist. Oversaw all controlled substances and regulatory inspections			
Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			
Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Cynthia Smith, certify that as the designated representative for

Critical Care Systems, LLC d/b/a Option Care Utah

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CA I am at least 21 years of age;
3. CA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Cynthia Smith

Print Name (First, Last)

Cynthia Smith

Original Signature (electronic, copies or stamps not accepted)

5-13-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cynthia Smith

Print Name (First, Last)

Cynthia Smith

Original Signature (electronic, copies or stamps not accepted)

5-13-24

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Lake

I, Cynthia Smith, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Cynthia Smith

Original Signature

5-13-24

Date

Subscribed and Sworn to before me this 13 day of May, 2024.

Michelle Mazzenga

Notary Public Signature

OFFICIAL SEAL
MICHELLE A MAZZENGA
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES 03/22/2026
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Option Care

NV Pharmacy or Outsourcing facility license # (if applicable):

Physical Address: 2233 S. Presidents Drive, Suite B

City: Salt Lake City State: UT Zip: 84120

Mailing Address (if different from physical address): 3000 Lakeside Dr., Suite 300N

City: Bannockburn State: IL Zip: 60015

Telephone: (866) 978-9600 Toll Free # (NAC 639.708, NRS 639.23286): (866) 978-9600

Fax: (801) 978-0020 Contact Email: oc-peandl@optioncare.com

Website: optioncare.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Cynthia Smith

Supervising/Managing Pharmacist NV Pharmacist Registration #: 233338

Name of Person with direct knowledge of compounding procedures: Cynthia Smith

Email of Person with direct knowledge of compounding procedures: Cynthia Smith

Telephone of Person with direct knowledge of compounding procedures: (866) 978-9600

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☒ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Antibiotics
hydration
total parenteral nutrition
chemotherapy agents

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?

Pharmacist visually inspects completed CSP for the presence of particles, foreign matter, evidence of incompatibilities, other defects, container closure integrity, and any apparent defects. Note: this is originally done by the compounding technician but the pharmacist does the final check.

8. How often do you perform glove fingertip and medial fill testing?

Initially upon hire, then annually thereafter

9. What is your policy if an employee fails a glove fingertip or media-fill test?

employee ceases to compound. Reeducation and retesting of employee.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

see attached

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

see attached

12. Who performs the sterile compounding process at your facility?

trained pharmacy technicians

13. Who is responsible and accountable for the sterile compounding process at your facility?

designated person, such as pharmacy supervisor, pharmacy manager and/or pharmacy technician supervisor

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Option Care has vetted its pack out process. For overnight deliveries based on package size and number of ice packs to ensure viability of medication. We also have a specific pack out process and policy

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? biological safety cabinet		
2. Is your BSC or CACI vented 100% to the outside?	☒ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☒ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☒ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☒ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☒ Yes	☐ No
7. If yes, list the name of the device: equashield		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? At start of care, patient or caregiver is verbally instructed on the proper handling and disposal of hazardous drugs. Option Care also includes a flyer in the introduction packet regarding the mail back system that is utilized for disposal. This is reinforced again when patient is discharged off of service.		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Review clean room videos which include receipt, spill control of hazardous drugs and training modules regarding hand hygiene, PPE, compounding, labeling, packaging transport, dispensing, administration, deactivation/decontamination/cleaning/disinfecting disposal, list of hazardous drugs engineering controls, exposure prevention/reduction. Employees educated on safety date sheets and closed system, equashield used to compound. Employee is respirator fit tested and media fill/ gloved fingertip thumb test performed in BSL in negative pressure room.		

N

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

2. What sterilization methods are utilized at your facility?

3. Does your facility utilize biological indicators? ☐ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ELENA HUBBARD
Name of Person who Completed the Form

Pharmacy Manager
Title

Signature (copies or stamps not accepted)

12/8/23
Date

Board Use Only	Date Received: 3/27/24 Date Approved: _____ Approved By: _____

Q10:

Initial: complete companies in the electronic management system, i.e., Option Care clean room environment, review videos on clean room, complete critical points, review policies on clean room and microbiological monitoring, aseptic techniques, BUD, garbing and gowning, hand washing, gloved fingertip testing/personal media fill, pharmacy equipment (excramix); gloved fingertip thumb test and media fill test low/medium media fill, gloved fingertip thumb testing in BSL and negative pressure room.

Annual: complete sterile compounding practice series each quarter, gloved fingertip thumb testing, low/medium media fill, fingertip thumb testing in BSL and negative pressure room

Q11:

Daily: in the morning, prior to compounding all pecs are disinfected with sterile 70% IPA. The anteroom sink and pass through window are cleaned with sterile germicidal TB1000 in the morning and at the end of the day. Sterile germicidal TB1000 is used to clean all pecs, horizontal surfaces such as carts, door handle, floors, anteroom sink, pass trough window followed by sterile 70% IPA (includes all pumps within the Laminar flow hood)

Twice Monthly: sterile peridox (sterile spermicidal property) is used in place of sterile germicidal agent during daily cleaning.

Monthly: the entire pec and sec is cleaned (i.e., ceiling, floors, walls, racks, chairs, carts, pumps, hoods, sink, pass through window) with sterile peridox after the appropriate contact time, followed with sterile 70% IPA. This also applies to our negative pressure room. However, on the days chemo is compounded, the BSL in the negative pressure room is decontaminated at the end of the day twice with sterile peridox application, followed by sterile 70% IPA. The negative pressure room itself is decontaminated with sterile peridox followed by sterile 70% IPA

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-State	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Non-sterile Compounding
	☐ Location Change *	☐ Internet	■ Sterile Compounding
	☐ Name Change*	☐ Nuclear	■ Mail-Order Service
		☐ Other:	☐ Off-site Cognitive Services
	* If making a change, provide license #:		☐ Long Term Care
			☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Babcock Pharmacy LLC. dba Premier Pharmacy

Physical Address: 2425 Babcock Rd Ste 108A

City: San Antonio State: TX Zip: 78229

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 210-298-9000 Toll Free # (NAC 639.708, NRS 639.23286): 866-507-7364

Fax: 210-298-9001 Contact Email: kelby@premierrxsa.com

Website: www.premierpharmacysa.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Paulette Wells

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22514

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Paulette Wells	NV Pharmacist Registration #: 22514
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): _____

Corporation/Organization Name: Babcock Pharmacy LLC.

Mailing Address: 2425 Babcok Rd Ste 108A

City: San Antonio State: TX Zip: 78229

Telephone: 210-298-9000 Email: 210-298-9001

Contact Person Name: Reynaldo Lerma

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Member (title) for Babcock Pharmacy LLC.dba Premier Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Reynaldo Lerma

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/11/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Reynaldo Lerma

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

10/11/2023

Date

Board Use Only	Date Received: 10/30/23	Amount: $500 - check 1178

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Babcock Pharmacy, LLC (file number 803017888), a Domestic Limited Liability Company (LLC), was filed in this office on May 16, 2018.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on December 06, 2023.

Jane Nelson
Secretary of State

PREMIER PHARMACY

List of Officers:

Reynaldo Lerma- 50% owner
[redacted] Tornillo Dr
San Antonio, TX 78258

Guadalupe Nunez- 50% owner
[redacted] Garden Ridge Dr
San Antonio, TX 78266

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Babcock Pharmacy LLC. dba Premier Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 2425 Babcock Rd Ste 108A

City: San Antonio State: TX Zip: 78229

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 210-298-9000 Toll Free # (NAC 639.708, NRS 639.23286): 866-507-7364

Fax: 210-298-9001 Contact Email: Kelby@premierrxsa.com

Website: www.premierpharmacysa.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Paulette Wells

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22514

Name of Person with direct knowledge of compounding procedures: Kelby Wilson

Email of Person with direct knowledge of compounding procedures: Kelby@premierrxsa.com

Telephone of Person with direct knowledge of compounding procedures: 210-298-9001

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Semaglutide and Tirzepatide Injections. Possibly some vitamin injections.

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☑ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?

Name: EAGLE ANALYTICAL Services

Address: 11111 S. Wilcrest Dr.

City: Houston, I State: Texas Zip: 77099

Telephone: 800-745-8916

7. What is your procedure for visual inspection of compounded sterile products?

We check in front of white light and also UV light for particulates or percipitates in the solution.

8. How often do you perform glove fingertip and medial fill testing?

Glove fingertip testing every 6 months, media fill testing is done every 3 months.

9. What is your policy if an employee fails a glove fingertip or media-fill test? We retrain our employee/ technician on the sterile technique procedures and then retest the individual prior to them working anymore in the clean room. We also document the failure in their file.

10. Describe your initial and annual training program for all personnel performing sterile compounding: A new hire will receive written and verbal training along with manual supervision ensuring our facility standards are met. This training includes finger tip testing, media fill testing and visual inspection of garbing and manipulation procedures. This will occur at random and/or every 6 months. This will be kept in the employee file.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Once a month we perform a deep cleaning of the sterile lab. all primary and secondary engineering controls are cleaned with Decon Spore 200+ or Decon Quat 200c. We alternate each month and follow the manufacturers directions for use. For weekly cleaning, we use Peridox RTU and/or Steri Perox 6%. Daily cleaning with sterile IPA 70% Spray.

12. Who performs the sterile compounding process at your facility?

Certified pharmacy compounding technicians that have passed state Certification training course and also passed internal pharmacy testing.

13. Who is responsible and accountable for the sterile compounding process at your facility?

Trained and certified pharmacists with many years experience. PIC – Kelby Wilson Staff pharmacist – David E. Hall

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

We use shipping contains that include a styrofoam cooler inside of a cardboard outer layer. Inside cooler we use Cold Paks frozen to last 48-72 hrs. Bubble packing product and foil packets. Then ship UPS or Fedex overnight.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?

2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No

7. If yes, list the name of the device:

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

Semaglutide Injection (2mg, 5mg/ml)
Tirzepatide Injection 10mg/ml
Vit B12 Injection (methylcobalamin 1mg/ml)

2. What sterilization methods are utilized at your facility?

We sterilize using 0.2 micron filters pharmaceutical grade from PALL (Acrodisc®) filters.

3. Does your facility utilize biological indicators? ☐ Yes ☑ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kelby Wilson
Name of Person who Completed the Form

Pharmacist- in- Charge
Title

Signature (copies or stamps not accepted)

10/23/2023
Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *PREMIER PHARMACY* **License Number:** *32121*

Address: *2425 BABCOCK RD STE 108A, SAN ANTONIO, TX 78229* **Phone:** *(210) 298-9000*

Email:

Class of License: *A* **License Expiration:** *06/30/2024*

DEA #: *FP7735129* **DEA Expiration:** *03/31/2024*

Inspection Information

Type: *Compliance* **Purpose:** *Rank Change*

Date: *07/17/2023* **Arrival Time:** *9:00 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Kelby Wilson *PIC* *64823*

Witness

Jim Clark

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *PREMIER PHARMACY* **License Number:** *32121*

Class of License: *A*

Inspection Information

Type: *Compliance* **Purpose:** *Rank Change*

Date: *07/17/2023* **Arrival Time:** *9:00 AM* **Departure Time:** *10:30 AM*

Action Taken: *Pre-Inspection*

General Comments:

Pre-Inspection Checklist

Verify Owner/Owner's Representative ID *Yes*

Name	Title
: *Rey Letma*	: *Owner*

Verify PIC ID *Yes*

Name	Title
: *Kelby Wilson*	: *PIC*

1. The prescription department has adequate space for the size and scope of the pharmaceutical services provided by the pharmacy. *Yes*

2. Fixtures (i.e. shelving, countertops, etc.) for the storage of drugs, equipment, and supplies necessary to operate a pharmacy are installed. *Yes*

3. Electrical supply exists. *Yes*

4. A sink with hot and cold running water available exclusive of the restroom facilities. *Yes*

Comment

Advised to have sink with hot water of at least 105 f

5. Pharmacy arranged in an orderly fashion and kept clean. *Yes*

6. The prescription department is complete and contains the following required equipment and supplies including, but not limited to: *Yes*

6a. data processing system including a printer or comparable equipment; *Yes*

6b. refrigerator to be maintained within a range compatible with the proper storage of drugs requiring refrigeration; *Yes*

6c. adequate supply of child-resistant, light-resistant, tight, and, if applicable, glass containers;	*Yes*
6d. adequate supply of prescription labels with name, address, and telephone number of the pharmacy;	*Yes*
6e. appropriate equipment necessary for the proper preparation of prescription drug orders;	*Yes*
6f. metric-apothecary weight and measure conversion charts;	*Yes*
6g. if the pharmacy serves the public, the word "pharmacy" or similar word or symbol, as determined by the board, is displayed in a prominent place on the front of the pharmacy.	*Yes*
7. A reference library is on site and current:	*Yes*
7a. Texas Pharmacy Laws and Regulations (publication year: _____)	*Yes*

Publication Year
: *Online*

7b. Drug Interactions Reference (publication year: _____)	*Yes*

Publication Year
: *Online*

7c. General Information Reference (publication year: _____)	*Yes*

Publication Year
: *Online*

7d. Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations (if the pharmacy is compounding non-sterile preparations)	*Yes*

Comment

Advised to have current version

7e. General reference text on veterinary drugs (if the pharmacy dispenses veterinary prescriptions)	*Not Applicable*
7f. Basic Antidote Information and telephone number of the nearest Regional Poison Control Center.	*Yes*
8.If the pharmacy is compounding sterile preparations, the following references are also required:	*Yes*
8a. United States Pharmacopeia/National Formulary or USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding Sterile Preparations	*Yes*

Comment

Must have current version of all required USP Chapters

8b. Chapter 71 of the USP/NF concerning Sterility Tests	*Yes*
8c. Chapter 85 of the USP/NF concerning Bacterial Endotoxins Test	*Yes*
8d. Chapter 1163 of the USP/NF concerning Quality Assurance in Pharmaceutical Compounding	*Yes*

8e. Handbook on Injectable Drugs (publication year: _____) Publication Year : *Online*	*Yes*
8f. Specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy (e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs)	*Not Applicable*
9. Security Requirements can be met to assure the pharmacy will be locked by key, combination, or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site.	*Yes*
10. Pharmacy has basic alarm system with the off-site monitoring and perimeter and motion sensors. (Alarm must be activated). *If your city requires an alarm permit, provide a copy of the permit.	*Yes*
11. Written policies and procedures/SOPs for the pharmacy's security system that meet the requirements of Rule 291.33(b)(2)(E)	*Yes*
12. An area suitable for confidential patient counseling, if the pharmacy serves the general public	*Yes*
13. If compounding sterile preparations, the pharmacy has controlled area that meets the requirements in Rule 291.133 (d)(6)(A) if the pharmacy is compounding low-risk and medium-risk preparations or Rule291.133(d)(6)(B) if high-risk preparations are being compounded.	*Yes*
14. Certified primary engineering control device (e.g., laminar airflow work benches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators).	*Yes*
15. Certified clean room(s) (e.g. ante area, buffer area).	*Yes*

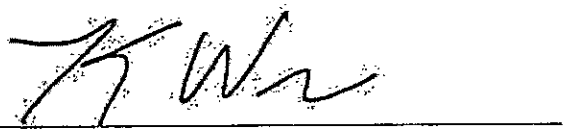
Discussion Items

The requirements of TSBP Rule 291.11 and Section 565.0591 of the Pharmacy Act regarding the operation of a pharmacy within 6 months of becoming licensed.	*Yes*
Corresponding Responsibility and the Red Flags checklist using references from the DEA RPh Manual, the Texas Controlled Substances Act, and TSBP Rules 291.29 and 291.34 (b).	*Yes*
Pharmacy will need to conduct an opening inventory on the first day of business.	*Yes*
Pharmacy will need to report all controlled substances to the PMP as required.	*Yes*

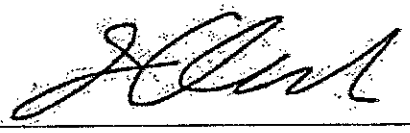
Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Kelby Wilson



James Clark

Texas State Board of Pharmacy

"Red Flags" Checklist for Pharmacies

YOU MIGHT BE A PILL MILL IF...

Check all that apply:

	(1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy
	(2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume.
	(3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs.
	(4) The prescriptions for controlled substances contain nonspecific or no diagnoses.
	(5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities.
	(6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions.
	(7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms.
	(8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy.
	(9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate.
	(10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants.
	(11) Drugs prescribed are inconsistent with the prescriber's area of practice.
	(12) The prescriber of the drugs is located a significant distance from your pharmacy.
	(13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action.
	(14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies.
	(15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office.
	(16) Multiple persons with the same address present prescriptions from the same prescriber.
	(17) Persons pay with cash or credit card more often than through insurance.
	(18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy).
	(19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies.
	(20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders.
	(21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday.
	(22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems.
	(23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility).

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

Updated 2/2018

Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
HALL, DAVID E.	22160	09/30/1976	10/31/2024	Staff	Active
KLATT, DUDLEY ILES	47607	07/30/2009	09/30/2025	Relief	Active
WILKINSON, CLAIRE LYDAY	45290	07/20/2007	09/30/2025	Relief	Active
WILSON, KELBY	64823	07/11/2019	07/31/2025	PIC	Active

Page 1 of 1 20 View 1 - 4 of 4

Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
CRUZ, TOMAS	115099	06/02/2004	10/31/2023	Staff	Active
DAVIS, HAILEY	184549	03/25/2011	12/31/2024	Staff	Active
FREEMAN, MICHAELA EVE	231190	05/30/2014	04/30/2024	Staff	Active
GOMEZ, ELDA MARIE	116890	05/18/2004	07/31/2024	Staff	Active
RAMIREZ, JESUS A	178186	09/10/2009	06/30/2025	Staff	Active
SANCHEZ, MIGUEL S	134557	05/10/2006	12/31/2023	Staff	Active
WILSON, MICHAEL SCOTT	350366	01/17/2023	01/31/2025	Staff	Active

Page 1 of 1 20 View 1 - 7 of 7

Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
BABCOCK PHARMACY, LLC	OWNER	,			
LERMA, REYNALDO	OFFICER	,			
NUNEZ, GUADALUPE JR	OFFICER	,			

Page 1 of 1 20 View 1 - 3 of 3

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

This certifies that the pharmacy named below is hereby licensed to operate as a Class **A** pharmacy.

License No. **32121** Expiration Date: **6/30/2024**

Balances: 1

PREMIER PHARMACY
2425 BABCOCK RD STE 108A
SAN ANTONIO TX 78229

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 32121

PREMIER PHARMACY

License Information

License Status Active
License # 32121
Expiration Date 06/30/2024
Date License Issued 06/20/2018

Address

2425 BABCOCK RD STE 108A
SAN ANTONIO, TX 78229
County BEXAR
Phone (210) 298-9000

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Community Sterile Compounding
Type of Ownership LLC
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
WILSON, KELBY

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	Yes
Translating services (Listed Below if Available)	

Spanish
Telecomm. for the deaf (TDD)

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the date in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 978304 32121 PREMIERPHARM 2019-01 01-2024.pdf
- 978304 32121 PREMIERPHARMACY 2021-06 06-2026.pdf
- 978304 32121 PREMIERPHARMACY 2023-07 07-2028.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	Yes
Ship Prescription Out of State	No
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	Yes
Compounding Sterile-Risk Level Med	Yes
Compounding Sterile-Risk Level High	Yes
Compounding Non-Sterile	Yes
24 Hour Service	No
Closed Door	No
Compounding, Office Use	Yes
Home Delivery	Yes
Infusion	No
Pharmacist Administered Immunizations	Yes
Veterinary Prescriptions	No
In-Patient Medication Orders	No

PREMIER PHARMACY
2425 BABCOCK RD
STE 108A
SAN ANTONIO, TX 78229-0000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP7735129	03-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	02-05-2021

PREMIER PHARMACY
BABCOCK PHARMACY LLC
2425 BABCOCK RD
STE 108A
SAN ANTONIO, TX 78229-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
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DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP7735129	03-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	02-05-2021

PREMIER PHARMACY
BABCOCK PHARMACY LLC
2425 BABCOCK RD
STE 108A
SAN ANTONIO, TX 78229-0000

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Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Babcock Pharmacy LLC. dba Premier Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2425 Babcock Rd Ste 108A

City San Antonio State TX Zip 78229

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Paulette Middle _____ Last Wells

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]Northwest Hwy Apt 1405

City Irving State TX Zip 75039

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Xavier University of Louisiana		1986-1989	
Address	**City**	**State**	**Zip**
1 Drexel Dr	New Orleans	LA	70125
Diploma/Degree obtained, if any			
Bachelor of Science			
School Name		**From - To (MM/YY – MM/YY)**	
St. Mary's Academy High School			
Address	**City**	**State**	**Zip**
6905 Chef Menteur Highway	New Orleans	LA	70126
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/23 thru present	[redacted] Northwest Hwy#1405	Irving	TX	75039
11/21 thru 01/23)	[redacted] East Round Grove Rd #2622	Lewisville	TX	75067
01/20thru 11/21	[redacted] Campus Blvd	New Orleans	LA	70126
5/08 thru 01/20	[redacted] Wallington Way	Lewisville	TX	75067

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Babcock Pharmacy LLC. dba Premier Pharmacy			09/23-Present	
Business Address		**City**	**State**	**Zip**
425 Babcock Rd Ste 108A		San Antonio	TX	
Phone	**Title**		**Number of Employed Hours**	
210-298-9000	Pharmacist in Charge (NV)		40 per week	
Description of Duties				
Representation of NV Pharmacist in Charge, Staff Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
VETERANS ADMINISTRATION			05/23-Present	
Business Address		**City**	**State**	**Zip**
4500 S Lancaster Rd		Dallas	TX	75216
Phone	**Title**		**Number of Employed Hours**	
214-742-8387	Staff Pharmacist		40 per week	
Description of Duties				
Staff Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
TPC Pharmacy			11/22-06/23	
Business Address		**City**	**State**	**Zip**
4200 Buckingham Rd		Fort Worth	TX	76155
Phone	**Title**		**Number of Employed Hours**	
844-387-9090	Staff Pharmacist		40 per week	
Description of Duties				
Staff Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
Empire Pharmacy Consultants			02/16-Present	
Business Address		**City**	**State**	**Zip**
1150 NW 72nd Ave #755		Miami	FL	33126
Phone	**Title**		**Number of Employed Hours**	
855-374-1029	Contract Pharmacist		40 per week	
Description of Duties				
Contarct Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
BAYLOR REHABILITATION HOSPITAL			05/13-0315	
Business Address		**City**	**State**	**Zip**
909 N. Washington Ave		Dallas	TX	75246
Phone	**Title**		**Number of Employed Hours**	
214-820-9300	Staff Pharmacist		40 Per week	
Description of Duties				
Staff Pharmacist				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Davita RX			06/07-09/18	
Business Address		**City**	**State**	**Zip**
1234 Lakeshore Dr		Coppell	TX	75019
Phone	**Title**		**Number of Employed Hours**	
972-538-8100	Staff Pharmacist		40 per week	
Description of Duties				
Staff Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
LEWISVILLE MEDICAL CENTER			12/09-01/10	
Business Address		**City**	**State**	**Zip**
500 W Main St		Lewisville	TX	75057
Phone	**Title**		**Number of Employed Hours**	
469-370-2000	Staff Pharmacist		40 per week	
Description of Duties				
Staff Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
VETERANS ADMINISTRATION -CMOP			12/04-02/06	
Business Address		**City**	**State**	**Zip**
4500 South Lancaster Road		Lancaster	TX	75216
Phone	**Title**		**Number of Employed Hours**	
214-742-8387	Staff Pharmacist		40 per week	
Description of Duties				
Staff Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
COMMUNITY CARE PHARMACY			06/03-12-04	
Business Address		**City**	**State**	**Zip**
2000 Canal St Suite g1-1200		New Orleans	LA	70112
Phone	**Title**		**Number of Employed Hours**	
504-758-3718	Staff Pharmacist		40 per week	
Description of Duties				
Staff Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
REGION I/III PHARMACY			01/02-12/04	
Business Address		**City**	**State**	**Zip**
1667 Tchoupitoulas St		New Orleans	LA	70130
Phone	**Title**		**Number of Employed Hours**	
504-301-2363	Staff Pharmacist		40 per week	
Description of Duties				
Staff Pharmacist				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Paulette Wells, **certify that as the designated representative for**

abcock Pharmacy LLC. dba Premier Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PW I am at least 21 years of age;
3. PW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Paulette Wells

Print Name (First, Last)

Paulette F. Wells

Original Signature (electronic, copies or stamps not accepted)

10-07-23

Date

10/07/2023

ROBERT PAUL BAKER
Notary Public, State of Texas
Comm. Expires 03-15-2026
Notary ID 133645260

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paulette Wells

Print Name (First, Last)

Paulette F. Wells — 10-07-23

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Dallas

I, Paulette Wells, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Paulette F. Wells — 10-07-23

Original Signature — **Date**

Subscribed and Sworn to before me this 7th day of October 2023

Notary Public Signature

10/07/2023

ROBERT PAUL BAKER
Notary Public, State of Texas
Comm. Expires 03-15-2026
Notary ID 133645260

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Babcock Pharmacy LLC. dba Premier Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 2425 Babcock Rd Ste 108A

City: San Antonio State: TX Zip: 78229

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: Reynaldo Middle: _____ Last: Lerma

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Tornillo Dr

City: San Antonio State: TX Zip: 78258

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Alice High School		08/1985 - 5/1988	
Address	**City**	**State**	**Zip**
1 Coyote Way	Alice	TX	78332
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
UTSA			
Address	**City**	**State**	**Zip**
1 UTSA Circle	S.A.	TX	78249
Diploma/Degree obtained, if any			
B.A. Psychology			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/23 - current	[redacted] blendon Dr	S.A.	TX	78 [illegible]
09/2018 - 06/23	[redacted] Tortillo Dr	S.A.	TX	78258
04/2012 - 09/2018	[redacted] Prospect Hill	S.A.	TX	78258
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

1988

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Rehmet Holdings			From - To (MM/YY – MM/YY): 7/2012 - Present
Business Address: 100 NE Loop 410 STE 1500	City: SA	State: TX	Zip: 78216
Phone: 210 392 0478	Title: Managing Member		
Description of Duties: all facets of business ownership			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Reynaldo Lerma

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/15/23

Date

Please have this section completed in the presence of a Notary Public.

State of TEXAS, ss. County of BEXAR

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of he license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/15/23

Date

Subscribed and Sworn to before me this 15 day of October 2023

Notary Public Signature

MARCELINE TALAMANTEZ
Notary ID #131416298
My Commission Expires
January 19, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

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Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Babcock Pharmacy LLC. dba Premier Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 2425 Babcock Rd Ste 108A

City San Antonio State TX Zip 78229

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Guadalupe Middle _____ Last Nunez

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Garden Ridge Dr

City San Antonio State TX Zip 78266

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Orange Grove High School		From - To (MM/YY – MM/YY): 1991-1994	
Address: 701 S Reynolds	City: Orange Grove	State: TX	Zip: 78372
Diploma/Degree obtained, if any: H.S Diploma			
School Name: University of Tx - San Antonio		From - To (MM/YY – MM/YY): 1991-2001	
Address: 1 UTSA Circle	City: San Antonio	State: TX	Zip: 78249
Diploma/Degree obtained, if any: B.S Kinesiology M.Ed Exercise Physiology			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Sep 2004 - Curr	[redacted] Garden Ridge	Garden Ridge TX	TX	78266
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Rehmet Holdings LLC			1995 – Current
Business Address	**City**	**State**	**Zip**
100 N Loop 410 Suite 1500	San Antonio	TX	78216
Phone	**Title**		
2106183423	Managing Member		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

1994

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Guadalupe Nunez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-14-23

Date

Please have this section completed in the presence of a Notary Public.

State of TEXAS, ss. County of BEXAR

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denia or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-16-23

Date

Subscribed and Sworn to before me this 10 day of 16, 2023

Notary Public Signature

MARCELINE TALAMANTEZ
Notary ID #131416298
My Commission Expires
January 19, 2026

(Seal)

Franchise Tax Account Status

As of : 10/05/2023 11:00:44

This page is valid for most business transactions but is not sufficient for filings with the Secretary of State

BABCOCK PHARMACY, LLC	
Texas Taxpayer Number	32067185580
Mailing Address	100 NE LOOP 410 STE 1500 SAN ANTONIO, TX 78216-4715
Right to Transact Business in Texas	ACTIVE
State of Formation	TX
Effective SOS Registration Date	05/16/2018
Texas SOS File Number	0803017888
Registered Agent Name	REYNALDO LERMA
Registered Office Street Address	100 NE LOOP 410, STE 1500 SAN ANTONIO, TX 78216

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

KW — I am the Pharmacist-in-Charge (PIC) of *PREMIER PHARMACY*, pharmacy license number *32121*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *07/17/2023*.

KW — I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

KW — I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

KW — If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

KW — I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: KW

Date: *07/17/2023*

Printed Name: *Kelby Wilson*

License No.(if applicable): *64823*

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☒ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Radiopharmaceuticals

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: RLS (USA) Inc.

Physical Address: 1828 Tribute Rd., Suite A-E

City: Sacramento State: CA Zip: 95815

Mailing Address (if different from physical address): NA

City: _____ State: _____ Zip: _____

Telephone: 916-648-3334 Toll Free # (NAC 639.708, NRS 639.23286): 1-800-242-8004

Fax: 916-648-3339 Contact Email: Sacramento@rls.bio

Website: RLS.BIO

Nevada Business License # (if applicable) NA

Supervising/Managing Pharmacist Name (NRS 639.220): Paul Fleming

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): NA

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Phuc Nguyen	NV Pharmacist Registration #: 21778
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): RLS Group Ltd.

Corporation/Organization Name: RLS (USA) Inc.

Mailing Address: 255 Primera Blvd., Suite #440

City: Lake Mary State: FL Zip: 32746

Telephone: 813-285-3065 Email: jonathan.lucas@rls.bio

Contact Person Name: Jonathan Lucas

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director of Regulatory Affairs (title) for RLS (USA) Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Glenn Sullivan, Ph.D.

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/9/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Glenn Sullivan, Ph.D.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4/9/2024

Date

Board Use Only	Date Received: 4/15/24	Amount: $500-cc

Corporate Officer List				
Name and Title	**Business Address and Phone Number**	**Home Address and Phone Number**	**SSN**	**DOB**
Stephen Belcher Chief Executive Officer	255 Primera Blvd, Suite 440, Lake Mary, FL 32746 Phone: 813-285-3065	[redacted] West St, Mobile, AL 36604 Phone: [redacted]	[redacted]	[redacted]
Mannon George Bankson III (Trey) Chief Operating Officer	255 Primera Blvd, Suite 440, Lake Mary, FL 32746 Phone: 813-285-3065	[redacted] Falls Crest Place, Auburn AL 36830 Phone: [redacted]	[redacted]	[redacted]
Glenn Sullivan Director of Regulatory Assurance	255 Primera Blvd, Suite 440, Lake Mary, FL 32746 Phone: 813-285-3065	[redacted] E. Main Street, Saint Paris, OH 43072 Phone: [redacted]	[redacted]	[redacted]

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	RLS (USA) INC.
Entity No.:	4312518
Registration Date:	08/28/2019
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	DELAWARE
Status:	Forfeited - FTB

The above referenced entity's powers, rights and privileges are forfeited in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may affect status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of April 09, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 198455537

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

Stockholders

Name	Title	Address	Email	% Ownership
Stephen Andrew Belcher	CEO	[redacted]Vest St., Mobile AL 36604	[redacted]	50%
Mannon George Bankson, III	COO	[redacted]Falls Crest Place, Auburn AL 36830	[redacted]	50%

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

LICENSE NO. PHY 57867
RECEIPT NO. 00187198

VALID UNTIL SEPTEMBER 01, 2024

RLS USA INC
1828 TRIBUTE RD STE A-E
SACRAMENTO CA 95815

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

)8/03/23
)8/03/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

2008

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 57867

NAME: RLS USA INC

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

1828 TRIBUTE RD STE A-E
SACRAMENTO CA 95815
SACRAMENTO COUNTY

ISSUANCE DATE

SEPTEMBER 1, 2020

EXPIRATION DATE

SEPTEMBER 1, 2024

CURRENT DATE / TIME

APRIL 11, 2024
3:24:12 PM

LICENSE RELATIONSHIPS

NAME: RLS USA INC

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 101598 **PRIMARY STATUS:** CLEAR

ADDRESS :
1828 TRIBUTE RD STE A-E
SACRAMENTO CA 95815
SACRAMENTO COUNTY

NAME: FLEMING, PAUL A

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 46654 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Sterile Compounding License

LICENSE NO. LSC 101598
RECEIPT NO. 00187202

VALID UNTIL SEPTEMBER 01, 2024

RLS USA INC
1828 TRIBUTE RD STE A-E
SACRAMENTO CA 95815

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

8/21/23
8/21/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

WPHLSC 09/30/19

2010

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 101598

NAME: RLS USA INC

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

1828 TRIBUTE RD STE A-E
SACRAMENTO CA 95815
SACRAMENTO COUNTY

ISSUANCE DATE

SEPTEMBER 1, 2020

EXPIRATION DATE

SEPTEMBER 1, 2024

CURRENT DATE / TIME

APRIL 11, 2024
3:23:16 PM

LICENSE RELATIONSHIPS

NAME: RLS USA INC

LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

LICENSE NUMBER: 57867 **PRIMARY STATUS:** CLEAR

ADDRESS :
1828 TRIBUTE RD STE A-E
SACRAMENTO CA 95815
SACRAMENTO COUNTY

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Outsourcing Facility ___ Wholesaler ___ Hypodermic

Date: 6/28/2023 Inspector: Rachel Powell

Firm: RLS USA INC Phone: (916) 648-3334

Address: 1828 TRIBUTE RD STE A-E City: SACRAMENTO Zip: 95815

Ownership: CORPORATION

Permit #: PHY57867 Permit Exp: 9/1/2023 DEA#: N/A DEA Exp: ___

Date of Self Assessment Form: ___ Other Permit #: N/A Date of DEA Inventory: ___

Hours M-F: 1AM-4PM Hours Saturday 4AM-12PM Hours Sunday: 4AM-12PM

PIC PAUL A FLEMING RPH46654 Administrator ___

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
TOMMY R THOMPSON	RPH53565	BONNIE L PIKINI	TCH51414
MATTHEW A ALEXANDER	RPH60631	SCOTT D SMOTHERMAN	TCH12604
MATTHEW W JAUREGUI	RPH60680		

Inspector Remarks:

Routine Pharmacy Inspection

- Portions of this inspection were performed remotely with data/documents supplied via e-mail by PIC Fleming
- PIC – Paul Fleming
  - Email – paul.fleming@rls.bio
  - Phone – 916-648-3334
- An onsite inspection was performed on 6/28/23 with the assistance of PIC Fleming.
- Simultaneous LSC renewal inspection performed, see LSC101598 for complete inspection report

General Information:

- Description of pharmacy – closed door nuclear pharmacy
- Sterile compounding – sterile to sterile, non-hazardous radiopharmaceuticals only, low and medium risk
  - Average number of kits/doses compounded daily – 20-25 kits/325 doses
  - Tc99m NaTcO4-, Tc99m PYP, Tc99m MDP, Tc99m DTPA, Tc99m SulfurColloid, Tc99m MAA, Tc99m Neurolite, Tc99m Fil S.Colloid, Tc99m MAG3, Tc99m Mebrofenin, Tc99m Sestamibi, Tc99m Ceretec, Tc99m Myoview, In111 Labeled WBC, In111 Octreoscan
- Pharmacy also does non-sterile compounding (I-131 capsules)
- Service area – Santa Rosa to Auburn (east to west), Chico to Modesto (north to south)
- Confirmed PIC and pharmacy are receiving subscriber alerts
- No controlled substances, no DEA license
- Vendors
  - Wholesaler – McKesson, Lantheus Medical Imaging, Jubilant Drax-Image, Lantheus, Sun Pharma, GE Healthcare

2012

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

- Waste – Stericycle
- Posted
  - Original license with renewal – sterile compounding and pharmacy
  - Notice to Consumer and Interpretive Services
- RAM license #4809-34, expires 9/6/2029
- No immunizations provided
- RPH/TECH ratio – 2 RPH, 2 TCH at beginning of inspection

Facility:

- Pharmacy security (key card entry, restricted access), cameras
- Restroom available
- Sink with hot/cold water

Records:

- Compounding and Pharmacy self-assessments – both completed 6/15/21
  - Per PIC Fleming, self-assessments for 2023 have been completed and are in the process of being signed by the owner
- Controlled substance reconciliation – N/A (no controlled substances)
- DEA 106 – N/A (no controlled substances)
- Quality assurance reports/incident reports – per PIC Fleming, none in the last 3 years
- Sample invoices reviewed
- All records stored onsite

Policies and Procedures:

- Theft/impairment, interpretive services, quality assurance, technician job description, temporary absence of RPH

Prescription Process & Drug Stock:

- CURES – N/A (no controlled substances)
- Reviewed drug supply area
- Drug supply reviewed monthly for expiration dates
- Prescription labels – meets the requirements for compounded sterile preparations (please refer to inspection report for LSC101598)
- Consultation – closed door pharmacy (no walk in patients) provides consultation to nuclear medicine department technologists and physician offices as needed
- Pharmacy computer system – Phargo

Discussion:

1. Discussed the importance of QA report access/maintenance and that records must be immediately retrievable (CCR 1711 & BPC 4125).

Education:

1. As a reminder, the self- assessments shall be performed before July 1 of every odd-numbered year. The Board will accept completion of either the currently adopted version OR the draft version. The draft version is likely to be a more helpful assessment to the pharmacy or wholesaler completing it.
2. New USP chapters were published 11/1/22 and will become official 11/1/23. This includes USP 795, 797 and 800. Please ensure compounding staff are educated and P&P's are updated accordingly.
3. The January 2023 issue of the Board of Pharmacy's newsletter, The Script, is now published online. A link to the newsletter can

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Gavin Newsom, Governor

INSPECTION REPORT

be found under "What's New" on the Board's website, www.pharmacy.ca.gov. Statutory Changes in Pharmacy Law for 2023 and important links for the revised USP chapters are included in the issue.

4. Law book: https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf
5. For questions pertaining to pharmacy law, please contact the board Monday through Thursday from 9am to 1pm. Email: ask.inspector@dca.ca.gov (Include name, organization, phone, and best time to call) Fax: (916) 574-8618 Phone: (916) 518-3100
6. Please keep a signed copy of this inspection report on file and readily available for three years.
7. Recently Approved Changes in Regulations:
    1. CCR 1704 – Providing addresses (Email). Effective 4/1/2022.

Inspector Rachel Powell, PharmD, Inspector
California State Board of Pharmacy
(831) 574-9658
rachel.powell@dca.ca.gov

Pursuant to Business and Professions Code 4083, within 30 days of service of the order of correction, a licensee of the California State Board of Pharmacy may submit a written request for an office conference with the board's executive officer to contest the order of correction.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) PAUL FLEMING

Inspector (sign) Rachel Powell

Inspector (print) Rachel Powell

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
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Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy __X__ Hospital Pharmacy ____ Clinic ____ Outsourcing Facility ____ Wholesaler ____ Hypodermic ____

Date: 6/28/2023 Inspector: Rachel Powell

Firm: RLS USA INC Phone: (916) 648-3334

Address: 1828 TRIBUTE RD STE A-E City: SACRAMENTO Zip: 95815

Ownership: CORPORATION

Permit #: LSC101598 PHY57867 Permit Exp: 9/1/2023 DEA#: N/A DEA Exp: ____

Date of Self Assessment Form: ____ Other Permit #: N/A Date of DEA Inventory: ____

Hours M-F: 1AM-4PM Hours Saturday 4AM-12PM Hours Sunday: 4AM-12PM

PIC PAUL A FLEMING RPH46654 Administrator ____

RPH Consultant

Staff	RPH Name:	License #:	Staff Name:	License #:
	TOMMY R THOMPSON	RPH53565	BONNIE L PIKINI	TCH51414
	MATTHEW A ALEXANDER	RPH60631	SCOTT D SMOTHERMAN	TCH12604
	MATTHEW W JAUREGUI	RPH60680		

Inspector Remarks:

Licensed Sterile Compounding Renewal Inspection

- Portions of this inspection were performed remotely with data/documents supplied via e-mail by PIC Fleming
- PIC – Paul Fleming
  - Email – paul.fleming@rls.bio
  - Phone – 916-648-3334
- An onsite inspection of the compounding area was performed on 6/28/23 with the assistance of PIC Fleming.
- Simultaneous routine inspection performed, see PHY57867

General Information:

- Description of pharmacy – closed door nuclear pharmacy
- Sterile to sterile – non-hazardous radiopharmaceuticals only
- Risk level – low and medium risk
- Average number of kits/doses compounded daily – 20-25 kits/325 doses
  - Tc99m NaTcO4-, Tc99m PYP, Tc99m MDP, Tc99m DTPA, Tc99m SulfurColloid, Tc99m MAA, Tc99m Neurolite, Tc99m Fil S.Colloid, Tc99m MAG3, Tc99m Mebrofenin, Tc99m Sestamibi, Tc99m Ceretec, Tc99m Myoview, In111 Labeled WBC, In111 Octreoscan
- Service area – Santa Rosa to Auburn (east to west), Chico to Modesto (north to south)
- Pharmacy also does non-sterile compounding (I-131 capsules)
- Confirmed PIC and pharmacy are receiving subscriber alerts
- No controlled substances, no DEA license
- Vendors
  - Wholesaler – McKesson, Lantheus Medical Imaging, Jubilant Drax-Image, Lantheus, Sun Pharma, GE Healthcare

- Waste – Stericycle
- Posted
  - Original license with renewal – sterile compounding and pharmacy
  - Notice to Consumer and Interpretive Services
- RAM license #4809-34, expires 9/6/2029
- Pest inspections completed monthly by Parish

Per documents provided by PIC Fleming:

- No physical layout changes to the sterile compounding facility in the past 12 months
- No changes to the sterile compounding equipment in the past 12 months
- No changes in types of sterile products compounded in the past 12 months
- No recalls related to the pharmacy's CSPs from the past 12 months
- No adverse events related to the pharmacy's CSPs from the past 12 months
- No FDA, DEA, or accreditation inspections in last 12 months
- No changes to list of sterile medications compounded in the past 12 months

Compounding Area:

- Gowning Room – ISO-8, positive pressure
  - Line of demarcation (change in floor color), sink, gowning supplies
  - Leads into 3 spaces – WBC Ante Room, Prep Room, Dispensing Room
- WBC Ante Room – ISO-7, positive pressure
  - Line of demarcation (tape on floor)
  - Leads into WBC Room
- WBC Room – ISO-7, positive pressure
  - Two ISO-5 hoods (Germfree BSC's)
  - One HEPA filtered pass thru to WBC prep room (unclassified)
  - One pass thru to Dispensing Room
- Prep Room – ISO-7, positive pressure
  - One pass thru to unclassified pharmacy area
  - One pass thru to Dispensing Room
- Dispensing Room – ISO-7, positive pressure
  - Three ISO-5 hoods (Envirco LAFW's)
  - One custom built mobile ISO-5 Envirco LAFW (generator hood)
  - Five pass thru's – 3 to unclassified pharmacy area, 1 to WBC Room, 1 to Prep Room

Certification: performed every 6 months. Last completed by CERTS on 12/20/22 under dynamic conditions.

- ISO-8 – Gowning Room
- ISO-7 – WBC Ante Room, WBC Room, Prep Room, Dispensing Room
- ISO-5 PEC's – two BSC's, three LAFW, one custom LAFW (generator hood)
- Non-viable air sampling performed
- Tested for HEPA filters leak, ACPH, differential pressures
- Video of smoke studies reviewed onsite
- Viable air and surface sampling performed
  - No growth for air samples
  - Growth within acceptable limits on one surface sample on the generator table in the Dispensing Room
- Certification recently completed on 6/14/2023 – report pending

Items Reviewed:

- Previous inspection

- Compounding and Pharmacy self-assessments – both completed 6/15/21
    - Per PIC Fleming, self-assessments for 2023 have been completed and are in the process of being signed by the owner
- Compounding Records – master formula and compounding log examples:
    - Tc99m Myoview (15-04/26/2023, lot 1*A)
        - Documentation in support of extension of BUD, 18 hours
    - Tc99m MAG3 (14-04/26/2023, lot 1*A)
        - Documentation in support of extension of BUD, 15 hours
    - Tc99m MDP (32-04/26/2023, lot 1*B)
        - Documentation in support of extension of BUD, 15 hours
    - Tc99m Mebrofenin (21-04/26/2023, lot 1*A)
        - Documentation in support of extension of BUD, 18 hours
- Labels – reviewed onsite – route, storage, BUD, and compounded by pharmacy verbiage. Lot # listed as the Control #
- References materials readily available
- Reviewed the following for March and April 2023:
    - Room, refrigerator, freezer, and incubator temperatures
    - Differential pressures
    - Dose calibrator constancy logs
    - Cleaning logs – daily/monthly cleaning regimen, hoods/rooms
        - All cleaning done by pharmacy staff (no EVS)
- Cleaning agents used:
    - Germicidal – Envirocide, PREempt RTU, Decon Quat 200C
    - Disinfecting – sIPA
    - Sporicidal – Peridox RTU, Decon Spore 200 Plus
- Quality Assurance – End-Product Testing
    - QC (bound result) reviewed for date range of 4/17/23-5/5/23
    - Sterility testing last performed 2/15/23

Items Observed:

- Visual inspection of compounding areas and hoods
- No active compounding occurring at the time of the inspection
- Staff garbing and gowning/handwashing – observed RPH Fleming
    - Lint free towels, nail picks, and persistent-activity alcohol based surgical scrub
- Sterile product storage
- Pressure differentials between rooms
- Hot/cold running water
- Eye wash area
- Dedicated cleaning supplies

Policies and Procedures Reviewed:

- Annual review of Policies & Procedures by PIC, last reviewed completed on 2/10/23
- Hand hygiene and garbing
- Facility & Equipment cleaning & sanitizing
- Plan for drug recall
- QA – validation through RCP testing (purity/stability)
- QA – sterility
- Equipment maintenance, storage, calibration, cleaning, and disinfection
- Beyond Use Dating
- Action level for CFUs detected during viable surface sampling, glove fingertip, and viable air sampling

- Action to be taken when CFU's have been exceeded for viable air, viable surface, or glove fingertip sampling

Training: Viewed for RPH Alexander and TCH Pikini

- Gloved fingertip/media fill
- Aseptic technique/compounding competencies
- Didactic and math skills assessment

Discussion:

1. Certification recently occurred on 6/14/23, report pending. Please email completed report and smoke study videos once received.
2. Discussed ensuring nail pick is used to clean under the nails during each instance of hand hygiene.

Education:

1. As a reminder, the self- assessments shall be performed before July 1 of every odd-numbered year. The Board will accept completion of either the currently adopted version OR the draft version. The draft version is likely to be a more helpful assessment to the pharmacy or wholesaler completing it.
2. New USP chapters were published 11/1/22 and will become official 11/1/23. This includes USP 795, 797 and 800. Please ensure compounding staff are educated and P&P's are updated accordingly.
3. The January 2023 issue of the Board of Pharmacy's newsletter, The Script, is now published online. A link to the newsletter can be found under "What's New" on the Board's website, www.pharmacy.ca.gov. Statutory Changes in Pharmacy Law for 2023 and important links for the revised USP chapters are included in the issue.
4. Send notification of all recalls, ADRs, and complaints to: compounding.report@dca.ca.gov
5. Law book: https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf
6. For questions pertaining to pharmacy law, please contact the board Monday through Thursday from 9am to 1pm. Email: ask.inspector@dca.ca.gov (Include name, organization, phone, and best time to call) Fax: (916) 574-8618 Phone: (916) 518-3100
7. Please keep a signed copy of this inspection report on file and readily available for three years.

Please send all action items and/or corrections to Inspector Powell at rachel.powell@dca.ca.gov by end of business **7/12/23.**

Inspector Rachel Powell, PharmD, Inspector
California State Board of Pharmacy
(831) 574-9658
rachel.powell@dca.ca.gov

Pursuant to Business and Professions Code 4083, within 30 days of service of the order of correction, a licensee of the California State Board of Pharmacy may submit a written request for an office conference with the board's executive officer to contest the order of correction.

Licensee Remarks:

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) PAUL FLEMING

Inspector (sign) Rachel Powell

Inspector (print) Rachel Powell

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 6/28/2023 Permit #: LSC101598

Time of Day: 8:40 AM

Name as shown on permit: **RLS USA INC**

Address: 1828 TRIBUTE RD STE A-E City: SACRAMENTO

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. **CCR 1250.42.** Compounding Area for Parenteral Solutions. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall: Have non-porous and cleanable surfaces, walls, floors and floor coverings.

In that at the time of inspection, there were numerous cracks/crevices in the flooring throughout the clean room area (including the junctions of the flooring under the doors) and gaps along the floor/wall junction (Dispensing Room, WBC Room, WBC Ante Room, Gowning Area). The green taped line of demarcation in the WBC Ante Room was partially missing/pealing and there was visible debris/residue on the floor where the tape had been. Additionally, there was visible dust/debris in the Gowning Room on the lower shelf of the cart and on the outer packaging of the coveralls. Please review the entire clean room area and have all affected areas repaired/replaced/cleaned/sealed and provide before and after photos.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) Rachel Powell

Inspector (print) Rachel Powell

Date 6/28/2023

Signed

Print Name PAUL FLEMING

Title PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

Corrective actions to the 6/28/2023 CA BOP Sterile Compounding Inspection noted deficiency:

- Cracks/crevices in flooring throughout the clean room area
- Gaps along the floor/wall junction
- Line of demarcation tape in poor condition
- Visible dust/debris identified in the gown (ante) room

All noted deficiencies in the clean room environment were corrected. As requested, before and after pictures were taken and provided by email to the inspector prior to issuance of the sterile compounding permit.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: RLS (USA) Inc.

NV Pharmacy or Outsourcing facility license # (if applicable): NA

Physical Address: 1828 Tribute Road, Suite A-E

City: Sacramento State: CA Zip: 95815

Mailing Address (if different from physical address): NA

City: State: Zip:

Telephone: 916-648-3334 Toll Free # (NAC 639.708, NRS 639.23286): 1-800-242-8004

Fax: 916-648-3339 Contact Email: Sacramento@rls.bio

Website: RLS.BIO

Nevada Business License # (if applicable) NA

Supervising/Managing Pharmacist Name (NRS 639.220): Phuc Nguyen

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21778

Name of Person with direct knowledge of compounding procedures: Paul Fleming

Email of Person with direct knowledge of compounding procedures: Paul.Fleming@rls.bio

Telephone of Person with direct knowledge of compounding procedures: 916-648-3334

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☑ Low ☐ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☑ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Radiopharmaceuticals only prepared or compounded in compliance with USP<825>.

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☑ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?
Name: NA
Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Visual inspection of Radiopharmaceuticals is completed in compliance with radiation safety ALARA principals.

8. How often do you perform glove fingertip and medial fill testing?

Every 12 months

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Immediate notification of the PIC, investigation for cause, corrective action(s) identified and taken as needed to prevent re-occurrence, retraining as required, retesting performed and passing results obtained prior to initiating or resuming product preparation or dose drawing duties.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

All new hire personnel performing sterile compounding must be licensed or registered in compliance with local regulations. Initial training is assigned based on job title/duties performed through an electronic platform. Personnel are trained on all policies and procedures associated with their job duties prior to performing those duties. Annual retraining is tracked, completed, and maintained using the electronic platform.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See attached CASOPs 6.4.1, 6.4.1.1, and 6.4.1.2.

12. Who performs the sterile compounding process at your facility?

All products are prepared by or under the direct supervision of the licensed, authorized nuclear pharmacist on duty.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The PIC is responsible and accountable for the sterile compounding process.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

RLS (USA) Inc. is a Nuclear Pharmacy dispensing radiopharmaceuticals in compliance with USP<825>. All transportation of prepared radiopharmaceuticals are completed by trained staff or contracted courier services in climate controlled vehicles in DOT-7A, Type A certified packaging designed and tested to maintain the quality and integrity of the product. Where temperature monitoring is required, RLS (USA) Inc. utilizes appropriate ColdMark Indicators to ensure proper temperature is maintained during shipping.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? NA		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

NA

2. What sterilization methods are utilized at your facility?

3. Does your facility utilize biological indicators? ☐ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kristin Anson

Name of Person who Completed the Form

Quality Manager

Title

Signature (copies or stamps not accepted)

4/10/2024

Date

Board Use Only	Date Received: 4/5/24 Date Approved: _____ Approved By: _____

CASOP 6.4.1 Cleaning & Disinfecting the Clean Room

I. Purpose

To describe the frequency, methods and materials required to clean and disinfect the ISO Classified aseptic processing environments.

II. Scope

This applies to all Nuclear Pharmacy sites in California.

III. Responsibility

It is the responsibility of the Business Unit Manager or designee to oversee policy compliance for personnel under his/her supervision. All pharmacy staff members and contractors will adhere to these guidelines and instructions. The Quality Assurance department will regularly perform audits to ensure compliance.

IV. Definitions:

A. **BOP** – Board of Pharmacy
B. **Classified Area** – Any area that meets ISO classification air quality requirements
    a. ISO S: 3520 particles per cubic meter e.g., LFH and BSC
    b. ISO 7: 352,000 particles per cubic meter e.g., dispensing and WBC processing room
    c. ISO 8: 3,S20,000 particles per cubic meter e.g., prep and gown room
C. **Cleaning** – Removal of dirt, dust, debris, or residue
D. **Clean Room** – An environment with a controlled level of dust and other contaminants
E. **Containment Box** – A sealed plexi-glass box system used to contain the heat block while heating of radiopharmaceutical products.
F. **Continuous Compounding (CC)** – Sterile compounding/dispensing lasting greater than 30 minutes
G. **Direct Compounding Area** – The critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered first air.
H. **ISO** – International Organization for Standardization.
I. **LFH** – Laminar Flow Hood.
J. **PEC**- Primary Engineering Control- a device/zone providing ISO Class 5 environment for sterile compounding, e.g., LFH, generator laminar flow hoods and biological safety cabinets
K. **Restricted Area** – Any controlled access area for the protection of individuals from exposure to radiation and radioactive materials.
L. **Sanitization** - The wiping of surfaces with an appropriate disinfectant from list A or B to reduce microbial contamination.
M. **SEC**- Secondary Engineering Control provide ISO Class 7 or 8 environments in which PECs are located, e.g., ISO 7 and 8 buffer and gown rooms
N. **Sterile Agent** – Cleaner or disinfection that has been filtered to 0.2 microns, gamma irradiated, and packaged in spray or aerosol single use containers that prevent the introduction of potentially contaminated room air.
O. **Stock Vial or Kit** – A vial or kit of vials containing product ingredients for preparation/dispensing

V. Related Documents:

As listed in CASOP 6.4.1.1 and CASOP 6.4.1.2

VI. Equipment and Materials:

As listed in CASOP 6.4.1.1 and CASOP 6.4.1.2

VII. Procedure

A. Documentation
   1. ISO Classified area and hand hygiene sink cleaning/disinfecting shall be documented on the appropriate approved form as indicated in CASOP 6.4.1.1 and CASOP 6.4.2.2.
      a. Retain documentation per SOP 1.4.1.
   2. Cleaning of areas outside and immediately surrounding the ISO Classified area may be documented on a site-specific cleaning checklist such as Attachment B of this procedure.
      a. No document retention requirement for areas outside and surrounding the ISO Classified area

B. Timing/Frequency
   1. Aseptic processing areas shall be cleaned/disinfected at the minimum timing/frequencies as listed in CASOP 6.4.1.1 and CASOP 6.4.1.2.
      a. If aseptic activities are not performed daily, daily cleaning and disinfection shall be completed before initiating activities.
   2. For the purposes of cleaning and disinfecting, the following definitions apply:
      a. Daily- each calendar day of use
      b. Weekly- each calendar week
      c. Monthly- each calendar month
   3. If a required task frequency exceeds the defined parameters in this procedure, the deviation will be identified in a note to file and the pharmacist in charge or designee will review.
   4. Areas outside but immediately surrounding the clean room shall be maintained in a clean manner to support the cleanliness of the ISO Classified areas at timing/frequency determined by the facility.

C. General Principles of cleaning the immediate area surrounding the clean room
   1. Follow storage and handling of clean room supplies as detailed in SOP 6.4.2.
   2. Keep floors and countertops immediately surrounding the clean room, as clean as possible to avoid dirt and debris inadvertently being carried inside the clean room.
   3. Adhesive-coated tacky mats shall be installed at each personnel and cart entrance to the clean room. As foot traffic or wheels pass over the surface, the non-transferring adhesive traps dirt.
      a. When the exposed layer is completely used, peel it off to expose a clean layer.
      b. Tacky mat sheets should be replaced daily as part of the cleaning of the ante room.
      c. Tacky mat should be replaced immediately when excessive contamination is noticed.
      d. Tacky mats shall never be placed inside an ISO classified area.

D. General Principles of Cleaning and Disinfection of the Clean Room
   1. Always check for radioactive contamination prior to cleaning or disinfecting.
      a. If radioactive contamination is identified, follow SOP 4.1.1 Facility Wipes and Surveys and SOP 4.1.2 Radiation Events
   2. All cleaning/disinfection and mopping will start in the cleanest area of the environment and move toward the less clean area of the environment.
   3. Cleaning/disinfection tasks are generally completed from top to bottom, and back to front.
      a. Hood cleaning/disinfection is outlined in CASOP 6.4.1.1.
      b. Rooms cleaning/disinfection is outlined in CASOP 6.4.1.2.
   4. Cleaning/disinfection of the Dispensing and WBC rooms shall not be performed during compounding or dose drawing activities.

a. Compounding or dose drawing activities may resume after the required contact time for the cleaning agent used.
b. To prevent cross contamination, mop heads and other disposable, non-cleanable, cleaning materials and supplies used in the WBC areas shall not be used in other areas of the clean room.
i. Cleanable supplies such as cleaning/disinfecting agent spray bottles, and mop handles may be used in other areas of the clean room only after thorough cleaning and disinfection.

5. Horizontal work surfaces must be wiped each day in each room to remove any dust or debris that may have settled on the surface.
a. Operators shall move supplies and equipment that are moveable to facilitate cleaning/disinfecting
b. Use the same front leading edge of a wiper or mop cover with each wipe
c. Wipe in one direction, carefully wiping around any non-moveable equipment
d. Each wipe should overlap approximately 25% with the previous wipe
6. Contact surfaces are those surfaces that are likely to be touched by employees and must be wiped each day to remove any possible touch contamination.
7. All reusable cleaning equipment such as mop handles and Easy Reach tool handles shall be cleaned and disinfected before and after use.
8. All non-reusable/disposable cleaning supplies, mop heads, and covers will be:
a. Disposed of after use
b. Surveyed for radioactive contamination prior to final disposal
c. Radioactive contaminated material will be handled according to current policies
9. Floors should be mopped using side to side motions wherever possible:
a. Always use the same leading edge of the floor mop head and overlap wipes to cover all areas with the cleaning agent, working backward toward the exit.
b. Where side to side motions cannot occur because of equipment placement, straight line overlapping wipes are appropriate.
c. Operators should not walk on freshly wet mopped floors.
d. Microfiber floor mop head covers must be changed when visibly soiled to ensure proper removal of dirt and debris.

E. General Principles Regarding Agents used to Clean/Disinfect the Clean Rooms
1. Cleaning and disinfecting agents must be approved through the MOC process prior to use in aseptic processing areas.
a. Approved agents are listed by category in Attachment A of this procedure
b. During product shortages, short term agent approval must be requested through the Quality Department
2. Agents shall be used and stored according to product labeling and site safety procedures.
3. All appropriate PPE per the product labeling and safety data sheet, including safety glasses shall be worn when handling or using agents.
4. Storage and handling of **non-sterile** agents and wipers shall follow these general rules:
a. Shall be used to clean and disinfect ISO Class 7 & 8 Environments
b. Shall not be used in ISO 5 Environments
c. In original manufacturer's spray bottles may be used up to the labeled manufacturer's expiration date

d. Transferred into new, clean chemical resistant spray bottles shall be properly labeled and given a maximum 2-month expiration or the manufacturer's recommended expiration, whichever is less

5. Storage and handling of **sterile agents** shall follow these general rules:
   a. Shall be used to clean and disinfect ISO Class 5 Environments
   b. In original manufacturer's spray bottles are single use and shall not be refilled
   c. Must be labeled with the open date and manufacturer's recommended expiration after opening or 2-month expiration, whichever is less. This is also considered the "in-use time".
   d. Sterile products not completely used prior to the "in-use time" shall be considered non-sterile and may be used in ISO Class 7 & 8 areas up to the manufacturer's product expiration.
   e. Spray bottles not pre-assembled shall be assembled in accordance with the manufacturer's instructions. If no instructions are provided, assemble according to the following:
      i. The outer product wrapper shall be cleaned and disinfected as the product is introduced into the cleanroom
      ii. The operator shall wear aseptic garb and use aseptic technique
      iii. The product shall be placed inside an ISO 5 PEC as the outer wrapper is removed.
      iv. Once inside the ISO 5 PEC, remove bottle from inner wrapper and place upright in first air
      v. Remove product cap; do not touch product seal and ensuring seal is in first air
      vi. Remove trigger sprayer from inner wrapper, avoid touch contamination of any parts that will be introduced into the product
      vii. Use sprayer straw to puncture the center of the bottle seal and tighten sprayer to bottle.
         1. Most sprayer seals are puncturable and sterility will not be compromised if properly handled
         2. Use judgement to determine if seal must be removed for assembly.
6. A sporicidal agent shall be used at least once each month to clean and disinfect all surfaces and items in all ISO Classified areas.
7. Wipers and mops shall be wetted with the agent being used. Agents shall not be sprayed or poured directly onto surfaces unless specifically allowed or required by the procedure.
8. Dry wipers shall only be wetted with one agent
9. Prewetted wipers shall not be wetted with a different agent
10. Surfaces shall be visibly wetted with the agent without dripping and shall remain wet for the required contact time.
11. All agents shall be ready-to-use (RTU) or premeasured/preassembled formulations and shall not be diluted or altered.
    a. If concentrated non-sterile agents are used due to shortages or out of stock situations,
       ii. The manufacturers labeling must be followed for proper dilution
       iii. A log must be maintained that records:
          1. The identity, lot number and volumes of the agent and diluent
          2. Date and time of dilution
          3. Expiration- per manufacturers labeling requirements or 24 hours if none is provided
       iv. Only new sterile syringes shall be used to measure agents for dilution
       v. Clean, chemical resistant containers must be used to store diluted agents
       vi. Containers must be properly labeled per SOP 5.1.8 Chemical Management

12. All agents exceeding the manufacturers or pharmacy assigned expiration must be removed from the clean room environment.
    a. Agents exceeding expiration may be used in other areas of the facility as determined appropriate by local management but shall not be used to support the clean room, i.e., used to disinfect items placed in pass thrus.
13. Approved cleaning agents listed in attachment A of this procedure may be used to remove residues as needed left by cleaning/disinfecting agents.

F. Special Cleaning Notes and Considerations for Areas Outside the Clean Rooms
1. Care must be taken when procedures require operators to bend down to reach low areas.
    a. Operators must familiarize themselves with obstructions in the area that may cause injury.
2. Areas immediately surrounding the clean room perimeter shall only contain essential items
3. Paper shredders and other particulate generating activities or materials such as corrugated cardboard storage or manipulation are prohibited within 10 feet of a pass through or doorway into the clean room.
4. A routine extermination program should be implemented upon findings of infestations in any areas of facility.
5. A cleaning checklist may be used for areas outside the clean room but maintaining this document is not a procedural requirement.
    a. Refer to Attachment B of this procedure for a checklist template

G. Maintenance of HEPA Filtered Clean Room Canister Vacuum
1. Follow the manufacturer's instructions for use and filter replacement.
2. Document filter replacements on Form 111 Clean Room Air Filter Maintenance Log.

XIII. Training

All employees shall review this procedure prior to initial site demonstration training.

LIST OF ATTACHMENTS

Attachment A: Approved Cleaning and Disinfecting Agents for Clean Room Environments
Attachment B: Cleaning Outside Clean Room Task List

DOCUMENT HISTORY		
Version	**Date**	**Brief Description of Change**
1.0	1 June 2020	New Procedure
2.0	15 Sept 2021	Include Remediation requirements, reference new form for investigation documentation, adding approved cleaner for residues, Removed Foam Mop Head from use BSC and LFH cleaning to include top grate. Removed ISO 5, 7 and 8 cleaning instructions and moved to separate sub procedures.
2.1	1 Nov 2021	Administrative
3.0	1 Mar 2022	Align with network SOP format, defined frequency, update of HEPA vacuum maintenance requirements to per MF requirements, update approved agent list.
3.1	1 Nov 2022	Remove Peridox RTU from attachment A

Attachment A: Approved Cleaning and Disinfecting Agents for Clean Room Environments

Approved Cleaning and Disinfecting Agents		
One step cleaning/disinfecting agents*	**Manufacturer**	**Contact Time**
PREempt RTU Solution and Wipes	Virox	10 min
PREempt Plus	Virox	1 min
Sporicidin Disinfectant Solution and Wipes	Contec	10 min
Envirocide	Metrex	3 min
Cavicide Solution and CaviWipes	Metrex	3 min
Cavicide 1 Solution and CaviWipes 1	Metrex	1 min
CaviWipes 2.0	Metrex	2 min
Decon Quat (All generations, SimpleMix formulations)	Veltek	10 min
*Decon Quat (All generations, SimpleMix formulations)- **Sterile**	Veltek	10 min
Decon Phene II (SimpleMix formulations)	Veltek	5 min
*Decon Phene II (SimpleMix formulations)- **Sterile**	Veltek	5 min
Decon Cycle (All generations, SimpleMix formulations)	Veltek	10 min
*Decon Cycle (All generations, SimpleMix formulations)- **Sterile**	Veltek	10 min
Sporicidal Cleaner/Disinfecting Agents*	**Manufacturer**	**Contact Time**
Decon Spore 200 Plus (SimpleMix formulations)	Veltek	10 min
*Decon Spore 200 Plus (SimpleMix formulations)- **Sterile**	Veltek	10 min
Disinfecting Agents*	**Manufacturer**	**Contact Time**
70% Sterile IPA	Various	NA
70% Non-sterile IPA	Various	NA
Cleaning Agents*	**Manufacturer**	**Contact Time**
Sterile water for irrigation	Various	NA
Decon Clean	Veltek	NA
Decon Clean- Sterile	Veltek	NA

***Non-radiopharmaceutical preparation:** USP<797> revision will require all cleaning and disinfecting supplies and agents used in an ISO 5 PEC to be sterile apart from tool handles and holders which must be cleaned and disinfected prior to use.

CASOP 6.4.1 Cleaning & Disinfecting the Clean Room

Attachment B: Cleaning Outside Clean Room Task List Week of: _____

DAILY Tasks	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Clean Countertops							
Empty Trash Cans							
Dry Mop/Sweep Floors							
Clean Pig Carts							
Disinfect Exterior of CR Pass-thru & Door Handles							
Check for & remove unnecessary items from immediate CR area (i.e., cardboard, paper, etc.)							
Disinfect Door Handles/Push Plates							
Disinfect Phones							
Disinfect Keyboards & Mice							
WEEKLY Tasks							
Disinfect Cart Pass-Thru Floor							
Clean Delivery Case Carts							
Wash/Change-out QC Developing Chambers							
Clean QC Area							
Clean DOT Station							
Wet Mop Restricted Area Floors							

CASOP 6.4.1.1 ISO Class 5 Cleaning & Disinfecting

I. Purpose

To describe the frequency, methods and materials required to clean and disinfect the ISO Class 5 environments.

II. Scope

This applies to all Nuclear Pharmacy sites in California.

III. Responsibility

It is the responsibility of the Business Unit Manager or designee to oversee policy compliance for personnel under his/her supervision. All pharmacy staff members and contractors will adhere to these guidelines and instructions. The Quality Assurance department will regularly perform audits to ensure compliance.

IV. Definitions:

A. **BOP** – Board of Pharmacy
B. **BSC**- Biological Safety Cabinet
C. **Classified Area** – any area that meets ISO classification air quality requirements
   a. ISO 5: 3520 particles per cubic meter e.g., LFH and BSC
   b. ISO 7: 352,000 particles per cubic meter e.g., dispensing and WBC processing room
   c. ISO 8: 3,520,000 particles per cubic meter e.g., prep and gown room
D. **Cleaning** – Removal of dirt, dust, debris, or residue
E. **Clean Room (CR)** – an environment with a controlled level of dust and other contaminants
F. **Containment Box** – A sealed plexi-glass box system used to contain the heat block while heating of radiopharmaceutical products.
G. **Continuous Compounding (CC)**– Sterile compounding/dispensing lasting greater than 30 minutes.
H. Daily- occurring every day the pharmacy is operating
I. **Direct Compounding Area** – the critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered first air.
J. **Disinfection**- Wiping surfaces with an appropriate disinfectant to reduce microbial contamination
K. **GLFH**- Generator Laminar Flow Hood
L. **IPA**- Isopropyl Alcohol
M. **ISO** – International Organization for Standardization
N. **LFH** – Laminar Flow Hood.
O. **PEC** - Primary Engineering Control is a device or zone that provides an ISO Class 5 environment for sterile compounding, e.g., LFHs, GLFHs, and BSCs
P. **Permanent Items**- refers to any item contained inside the ISO 5 LFH which due to factors such as size, weight, or installation within the LFH, are not removed for daily cleaning and disinfections
Q. **Restricted Area** – any controlled access area for the protection of individuals from exposure to radiation and radioactive materials.
R. **Run**- scheduled departure of customer deliveries
S. **SEC**- Secondary Engineering Control provides ISO Class 7 or 8 environments in which PECs are located, e.g., ISO 7 and 8 buffer and gown rooms
T. **Sporicidal Agent**- a chemical agent that destroys bacterial/fungal spores and kills all vegetative microorganisms when used at a sufficient concentration for a specified contact time.
U. **Sterile Agent** – An agent that has been filtered to 0.2 microns, gamma irradiated, and packaged in spray or aerosol single use containers that prevent introduction of potentially contaminated air.
V. **WB Shield**- fixed whole body shielding at the front of the LFH to protect worker from radiation

V. Related Documents:

A. Form 25: Laminar Flow Hoods & Biological Safety Cabinets Cleaning Log

VI. Equipment and Materials:

A. Sterile lint-free cloths/wipes (Dry and/or Pre-saturated)
B. Easy Reach Cleaning Tool with Sterile Lint-free mop covers
C. Microfiber clothes/wipes
D. Approved cleaning and disinfecting agents for clean room environments identified in CASOP 6.4.1 Attachment A

VII. Procedure

A. General Guidance
1. Sterile cleaning and disinfecting agents, wipers and mop covers shall be used on inside surfaces of ISO Class 5 PECs.
2. Sterile gloves must be worn when cleaning, disinfecting, and working within any ISO Class 5 PEC
3. ISO Class 5 PEC cleaning and/or disinfection shall be completed in the order listed.
4. After application of a sterile one-step cleaning/disinfecting agent in an ISO Class 5 PEC or on any tools/equipment to be introduced into an ISO Class 5 PEC, sterile 70% IPA shall be applied after the agent contact time to remove any residue.

B. LFH Cleaning/Disinfecting Frequency/Timing and Agents:

Process	Frequency/Timing	Agent
Daily LFH Cleaning/Disinfection	Daily, prior to first use	Approved **STERILE** EPA-registered one step cleaning/disinfecting agent identified in SOP CA6.4.1 Attachment A
	After certification or other service is complete, prior to use	
	When contamination is known or suspected	
Daily LFH Disinfection	After daily cleaning/disinfection to remove residue	Sterile 70% IPA
	Immediately prior to each production run	
	Immediately prior to preparation of non-radiopharmaceuticals	
LFH Continuous Compounding	Approximately every 30 minutes if a run takes greater than 30 minutes	Sterile 70% IPA
Monthly LFH Cleaning AND Disinfection	Monthly	Approved **STERILE** Sporicidal agent identified in CASOP 6.4.1 Attachment A followed by Sterile 70% IPA
	When the unit is moved, repaired, or major service is conducted	

C. Daily LFH Cleaning/Disinfection and Daily LFH Disinfection Procedure
1. Remove all removable tools, equipment, and supplies from the hood.
   a. The dose calibrator keypad, well, and pulleys are not considered "removable" equipment for daily cleaning.
2. Apply the appropriate approved agent to the wiper/mop cover as indicated in the chart above.

a. The Easy Reach tool must be used if the operator cannot reach all surfaces without leaning into the LFH, i.e., the operator's body should not break the plane of the front opening.
b. Rewet the wiper/mop cover as needed during this procedure to ensure all surfaces are thoroughly wetted without dripping.

3. Clean/disinfect stainless steel ceiling panels
   a. Starting where the ceiling meets the back wall, wipe from the ceiling center toward the left or right side with over lapping wipes, moving from the back to the front of the LFH.
   b. Move to the other side and wipe in the same manner from the center toward the opposite sidewall ensuring wipes also overlap with opposite side wipes in the center of the ceiling.
4. Clean/disinfect the backwall
   a. Begin by wiping the vertical bar separating the back wall of the LFH from top to bottom
   b. Starting at the upper left or right edge of the vertical bar, wipe horizontally along the top of the back wall toward the side wall. Continue wiping horizontally down the back wall, wiping in one direction with the same leading wiper edge and overlapping wipes as you work down the wall.
   c. Move the other side of the center bar and wipe the other side in the same way.
5. Clean/disinfect each side wall
   a. Starting at the ceiling in the back corner, wipe vertically or downward toward the deck moving toward the front of the hood with overlapping wipes.
   b. Move to the other side and wipe the other side wall in the same way.
6. Clean/disinfect permanent items within the LFH
   a. Using a saturated wiper, wipe all items that are not removed, working from the highest points down toward the deck and from the back to the front
   b. Permanent items include dose calibrator keypad, well, pulleys, and WB shield/support bars.
7. Clean/disinfect the deck surface
   a. Starting at the approximate center of the deck, wipe the deck surface from the center to the left or right side wall along the line where the deck meets the back wall. Continue wiping from the center of the deck to the outside wall using overlapping wipes as you work your way toward the front of the hood opening.
   b. Wipe in as straight a line as possible, carefully wiping around the dose calibrator well
   c. Pick up the dose calibrator keypad, wipe under, replace, and wipe keypad where it was touched
   d. Move to the other side and wipe the other side of the deck in the same way
8. If cleaning/disinfecting was completed with a one-step agent, immediately after the agent's contact time, repeat steps 3-7 using clean wipers or mop heads and sterile 70% IPA.
9. Clean/disinfect and/or disinfect tools, equipment, and supplies going back into hood
   a. When performing daily cleaning/disinfecting, wipe items with the one-step agent, allow contact time, then wipe with clean wiper and sterile 70% IPA and place in hood
   b. When performing LFH disinfections, wipe items with sterile 70% IPA and place in hood
10. Refer to table below for a brief summary of daily LFH cleaning/disinfection steps

Area	Motion
LFH Stainless Steel Ceiling	Horizontally, starting in the middle, middle to side, from back overlapping to front, each side
LFH Back	Center bar vertically. Walls horizontally, starting in the middle, from middle to side, from top overlapping to bottom, each side
LFH Side Walls	Vertically, top to bottom, from back overlapping to front, each side
LFH Permanent Items	Wipe anything permanent from top back to bottom front
LFH Deck	Horizontally, starting in the middle, middle to side, from back overlapping to front each side
LFH Tools, Supplies, etc.	Prior to introduction

D. LFH Continuous Compounding
   1. This procedure shall be performed when preparation or compounding procedure exceeds 30 minutes in duration.
   2. This procedure shall not disrupt an aseptic process but will be performed immediately after a process which exceeds 30-minutes, but further aseptic processing is going to be performed:
      a. Remove tools and supplies from the LFH deck.
      b. Disinfect the deck surface as described in section C of this procedure
   3. Disinfect tools and supplies as they are placed back inside the LFH

E. Monthly LFH Cleaning and Disinfection
   1. A monthly cleaning/disinfection procedure shall be completed on each LFH as indicated in this procedure using a sterile cleaning agent, a sterile sporicidal agent, and sterile 70% IPA listed in Attachment A of CASOP 6.4.1.
   2. Have the following supplies or similar approved supplies readily available:
      a. Sufficient supply of Easy Reach mop handles
      b. Sufficient supply of Easy Reach mop covers
         i. A separate mop cover is needed for each agent
         ii. Mop covers shall be changed during this procedure as indicated or if visibly soiled
      c. Puncture resistant gloves
      d. Sufficient supply of sterile wipers
      e. Sterile cleaning agent
      f. Sterile sporicidal agent
      g. Sterile 70% IPA
      h. Several clean empty carts to place tools, equipment and decking on
   3. Remove all tools, equipment and supplies from the LFH that are removable and place on a clean cart
      a. The dose calibrator well is not considered removable
   4. Don puncture resistant gloves and spray with sterile 70% IPA to continue
   5. Carefully remove the following and place on a clean cart:
      a. Front airflow grate
      b. Stainless-steel deck mid-section (tray)
      c. Rear airflow grate
      d. Cross supports
   6. Using wiping guidance listed in step 7 below, clean wipers, and Easy Reach mop covers saturated with an approved sterile cleaning agent listed in CASOP 6.4.1 Attachment A, remove, if necessary, visible particles, debris, or residue from the grates, supports, decking, and area below the deck.
   7. Using an approved sterile sporicidal agent from CASOP 6.4.1 Attachment A, wipe the following:
      a. Using a wiper saturated with the agent, wipe the outside surfaces of the well
      b. Using the Easy Reach tool saturated with the agent, wipe:
         i. the side plenum walls from top to bottom, back to front with overlapping wipes
         ii. the front plenum wall from top to bottom side to side with overlapping wipes
         iii. the bottom of the plenum from the back middle, wiping back to front working toward one side then repeating on the other side.
         iv. the top of the cross supports
      c. After the sterile sporicidal agent's contact time has been reached, repeat steps 7a-b using new clean wipers and mop covers saturated with sterile 70% IPA
      Note: For cleaning/disinfecting the plenum walls and bottom, only use the easy reach tool. Do not use wipers as the plenum may have sharp edges and an injury could occur.

8. Clean/disinfect the cross supports, grates, and bottom of the stainless-steel deck mid-section (tray) using the Easy Reach tool and mop cover saturated with the sterile sporicidal agent.
   a. Use extreme care when cleaning these pieces as they are very sharp
   b. Use the easy reach mop head saturated with the sterile sporicidal agent to wipe the top of the cross supports, and grates and the underside of the deck mid-section
      i. Do not wipe the underside of the supports or grates as they are very sharp and will tear the mop heads or wipers, generating particles/debris
      ii. Always use caution around sharp edges of the mid-section deck that has been cut to accommodate the dose calibrator well.
   c. After the sterile sporicidal agent's contact time, repeat steps 8a-b using the Easy Reach tool and a clean mop head saturated with sterile 70% IPA and immediately reinstall all pieces
9. Replace both Easy Reach tools with clean covers
   a. Perform a cleaning/disinfection of the LFH using steps listed in section C of this procedure and the sterile sporicidal agent.
   b. After the sterile sporicidal agent contact time, repeat the steps listed in section C of this procedure using a clean wiper or mop head and sterile 70% IPA
10. Wipe all tools, equipment and supplies with the sterile sporicidal agent allowing for the agents contact time, followed by a wipe with a clean sterile 70% IPA prior to placing them back inside the LFH

F. LFH Cleaning/Disinfection after Ceiling Service
   1. When service involves manipulations above the LFH stainless-steel ceiling grates, the following additional cleaning in addition to the monthly cleaning/disinfection shall be performed:
      a. Remove the ceiling grates and place on a clean stainless-steel cart
      b. Carefully wipe both sides of the grates with an approved sterile sporicidal agent using the Easy Reach tool with a clean mop cover
      c. After the sterile sporicidal agent's contact time and using a new Easy Reach tool mop cover, carefully wipe both sides of the grates with sterile 70% IPA
      d. Reinstall the ceiling grates and then complete the full monthly clean.

G. BSC Cleaning/Disinfecting frequency and agents used are based on the process being completed as outlined in this procedure:

Process	Frequency/Timing	Agent
Daily BSC Cleaning/Disinfection	Daily, prior to first use	Approved STERILE EPA-registered one step cleaning/disinfecting agent identified in CASOP 6.4.1 Attachment A
	After each blood labeling procedure	
	When contamination is known or suspected	
Daily BSC Disinfection	After daily cleaning/disinfection to remove residue	Sterile 70% IPA
	No greater than 30 minutes prior to each use	
Monthly BSC Cleaning AND Disinfection	Monthly	Approved STERILE sporicidal agent identified in CASOP 6.4.1 Attachment A followed by Sterile 70% IPA
	When the unit is moved, repaired, or major service is conducted	

H. Daily BSC Cleaning/Disinfection and Daily BSC Disinfection
   1. Remove all removable tools, equipment, and supplies from the hood.
      a. Set up Ge-68/Ga-68 generators are not removable while in active service
   2. Wet the wiper/mop cover with the appropriate agent listed in table above.
      a. Rewet the wiper/mop cover as needed during this procedure to ensure all surfaces are thoroughly wetted without dripping.
   3. Clean/disinfect the ceiling
      a. Start at the back left or right side and wipe horizontally from side to side, back to front with overlapping, single direction wipes
   4. Clean/disinfect the backwall
      a. Start at the top left or right side and wipe horizontally from side to side, top to bottom with overlapping, single direction wipes
   5. Clean/disinfect each side wall
      a. Starting at the top back corner and wipe vertically or downward toward the deck, back to front with overlapping, single direction wipes
   6. Using a saturated wiper, clean/disinfect any permanent items within the BSC such as an IV bag hanging rod if applicable, working from the top back to bottom front.
   7. Clean/disinfect the deck surface
      a. Starting at the back wall, wipe horizontally, side to side, back to front with overlapping wipes
   8. Clean/disinfect tools, equipment, and supplies
      a. When performing daily BSC cleaning/disinfecting, wipe items with the one-step agent, allow for contact time, then wipe with a clean wiper and sterile 70% IPA as they are placed back in the hood
      b. When performing BSC disinfections, wipe items with sterile 70% IPA as they are placed back in the hood
   9. Refer to table below for a brief summary of daily BSC cleaning/disinfection steps

Area	Motion
BSC Ceiling	Horizontally, side to side, from back overlapping to front
BSC Back Wall	Horizontally, side to side, from top overlapping to bottom
BSC Side Walls	Vertically, top to bottom, back overlapping to front
BSC Permanent Items	Wipe anything permanent from top back to bottom front
BSC Deck	Horizontally, side to side, back overlapping to front
BSC Tools, Supplies, etc.	Prior to introduction

I. Monthly BSC Cleaning/Disinfection
   1. A monthly cleaning and disinfection procedure shall be completed on each BSC as indicated in this procedure using a sterile cleaning agent, a sterile sporicidal agent, and sterile 70% IPA listed in CASOP 6.4.1 Attachment A
   2. Have readily available the following:
      a. Sufficient supply of sterile wipers
      b. Sterile cleaning agent
      c. Sterile sporicidal agent
      d. Sterile 70% IPA
   3. Remove all tools, equipment and supplies from the BSC and place on a clean table surface
      a. Set up Ge-68/Ga-68 generators are not removable while in active service
   4. Remove the BSC deck tray and place carefully on a clean table surface
      a. BSC's containing Ge-68/Ga-68 generators in active service, shall not be cleaned/disinfected under the tray or the tray bottom monthly, please skip to step 7.

b. BSC's used for elution of Ge-68/Ga-68 generators shall be cleaned/disinfected under the tray and the bottom of the tray when generators are removed from service and operators have access to the area below the deck.

5. Remove, if necessary, any visible particles, debris, or residue from the tools, equipment, supplies, deck tray and area below the deck tray, using a wiper saturated with a sterile cleaning agent listed in CASOP 6.4.1 Attachment A.
6. Clean/disinfect the area below the deck and the bottom of the deck tray using extreme care to avoid all sharp edges:
   a. Wet a wiper with the sporicidal agent and wipe the area below the deck carefully, wiping back to front with overlapping wipes.
   b. Wipe the bottom of the deck tray with overlapping wipes.
   c. After the sporicidal agent's contact time, repeat the procedure with a clean wiper and sterile 70% IPA, reinstall the deck tray.
7. Remove, if necessary, any visible particles, debris, or residue from the inside of the BSC with an approved sterile cleaning agent listed in SOP 6.4.1 Attachment A.
8. Perform a cleaning/disinfection of the inside of the BSC using the step listed in section H of this procedure using the sterile sporicidal agent.
   a. After the agent's contact time, repeat steps listed in section H of this procedure using a clean sterile wiper and sterile 70% IPA
9. Wipe all tools, equipment and supplies with the sterile sporicidal agent allowing for the agent's contact time, followed by a wipe with a clean sterile wiper and sterile 70% IPA prior to placing them back inside the BSC

J. GLFH Cleaning/Disinfecting frequency and agents used are based on the process being completed as outlined in this procedure:

Process	Frequency/Timing	Agent
Daily GLFH Cleaning/Disinfection	Daily, prior to first use	Approved STERILE EPA-registered one step cleaning/disinfecting agent identified in CASOP 6.4.1 Attachment A
	After certification or other service is complete, prior to use	
	When contamination is known or suspected	
Daily GLFH Disinfection	No greater than 30 minutes prior to each use	Sterile 70% IPA
Monthly GLFH Cleaning AND Disinfection	Monthly	Approved STERILE sporicidal agent identified in CASOP 6.4.1 Attachment A followed by Sterile 70% IPA
	When the unit is moved, repaired, or major service is conducted	

K. Daily GLFH Cleaning/Disinfection and Daily GLFH Disinfection
   1. Wet the wiper/mop cover with the appropriate agent listed above.

   a. Rewet the wiper/mop cover as needed during this procedure to ensure all surfaces are thoroughly wetted without dripping.
2. Clean/disinfect the ceiling
   a. Wipe from back to front with overlapping wipes
3. Clean/disinfect the backwall shield
   a. Start at either corner, wipe from the ceiling downward with overlapping wipes along the entire length of the shield
4. Clean/disinfect each side wall shield
   a. Starting at the ceiling in a corner, wipe downward with overlapping wipes along the length of each side wall.
5. Clean/disinfect the front shield
   a. Start at either corner, wipe from the ceiling downward with overlapping wipes along the entire length of the front shield
6. Using a saturated wiper, clean/disinfect generator shields and the generator tabletop under hood.
7. Clean/disinfect any tools, equipment, and supplies before introduction into the GLFH.

L. Monthly GLFH Cleaning/Disinfection
1. A monthly cleaning procedure shall be completed on the GLFH as indicated in this procedure using a sterile cleaning agent, a sterile sporicidal agent, and sterile 70% IPA listed in CASOP 6.4.1 Attachment A.
2. Remove, if necessary, any visible particles, debris, or residue from the inside of the GLFH, all generator shields, and the entire generator table with a sterile cleaning agent.
3. Wipe all areas using the same steps as listed in section K of this procedure using the sterile sporicidal agent.
4. Wipe all generator shields and the entire generator table with the sterile sporicidal agent.
5. After the sporicidal agent's contact time, wipe all areas using the same steps as listed in section K of this procedure using a clean sterile wiper and sterile 70% IPA
6. After the sporicidal agent's contact time, wipe all generator shields and the entire generator table with a clean sterile wiper and sterile 70% IPA.

XIII. Training

All employees shall review this procedure prior to initial site demonstration training.

LIST OF ATTACHMENTS

None

DOCUMENT HISTORY		
Version	**Date**	**Brief Description of Change**
1.0	15 Sept 2021	Reorganized procedure- separated out ISO 5 PEC cleaning from the main CASOP 6.4.1 into sub-procedure CASOP 6.4.1.1. Include Remediation requirements, reference new form for investigation documentation, adding approved cleaner for residues, Removed Foam Mop Head from use BSC and LFH cleaning to include top grate.
1.1	1 Nov 2021	Administrative
1.2	1 Mar 2022	Update to allow for greater flexibility in use of approved agents. Changes made to hood cleaning/disinfection steps to align with industry best practices and USP compliance.
1.3	1 Nov 2022	Added CA BOP definition of "Daily", PECs must be cleaned/disinfected each day of operations. Corrected cleaning procedure for LFH and BSC ceilings. Clarify requirement for Ge68/Ga68 generator PEC cleanings. Aligned PEC area wiping directions to align with network procedure. Added residue removal to BSC daily disinfection.

CASOP 6.4.1.2 Cleaning & Disinfecting ISO 7 & 8

I. Purpose

To describe the frequency, methods and materials required to clean and disinfect the ISO Class 7 & 8 aseptic processing environments.

II. Scope

This applies to all Nuclear Pharmacy sites in California.

III. Responsibility

It is the responsibility of the Business Unit Manager or designee to oversee policy compliance for personnel under his/her supervision. All pharmacy staff members and contractors will adhere to these guidelines and instructions. The Quality Assurance department will regularly perform audits to ensure compliance.

IV. Definitions:

A. **BOP** – Board of Pharmacy
B. **Classified Area** – Any area that meets ISO classification air quality requirements
   a. ISO 5: 3520 particles per cubic meter e.g., LFH and BSC
   b. ISO 7: 352,000 particles per cubic meter e.g., dispensing and WBC processing room
   c. ISO 8: 3,520,000 particles per cubic meter e.g., prep and gown room
C. **Cleaning** – Removal of dirt, dust, debris or residue
D. **Clean Room (CR)** – An environment with a controlled level of dust and other contaminants
E. **Containment Box** – A sealed plexi-glass box system used to contain the heat block while heating of radiopharmaceutical products.
F. **ISO** – International Organization for Standardization
G. **PEC** - Primary Engineering Control provides ISO Class 5 environment for sterile compounding, e.g., laminar flow hoods, generator laminar flow hoods and biological safety cabinets
H. **Disinfecting** - The wiping of surfaces with an appropriate disinfectant to reduce microbial contamination.
I. **SEC**- Secondary Engineering Control provides ISO Class 7 or 8 environments in which PECs are located, e.g., ISO 7 and 8 buffer and gown rooms

V. Related Documents:

A. Form 25: Laminar Flow Hoods & Biological Safety Cabinets Cleaning Log
B. Form 76, Daily/Monthly Cleaning Log

VI. Equipment and Materials:

A. Tiger Vac CR-1 ULPA Canister Vacuum with HEPA Filter Exhaust
B. Tiger Vac CR-1 ULPA Canister Vacuum paper filter bags #212500
C. Tiger Vac CR-1 ULPA Canister Vacuum cloth main filter #212502
D. Tiger Vac CR-1 ULPA Canister Vacuum ULPA filter #212304 and sealant
E. Clean room floor mopping: microfiber mop
F. Clean room ceiling wall cleaning: microfiber mop
G. Sterile lint-free cloths/wipes (Dry and/or Pre-saturated)
H. Easy Reach Cleaning Tool with Sterile Lint-free mop covers
I. Tacky Roll Mops 18"
J. Microfiber clothes/wipes
K. Tacky Mats (minimum size of 24"x 36")

L. Approved cleaning and disinfecting agents for clean room environments identified in CASOP 6.4.1 Attachment A

VII. Procedure

A. Daily Cleaning and Disinfection Procedure for ISO Class 7 and 8 Rooms

1. The order in which rooms are cleaned shall follow this guidance but the listed order need not be strictly followed, i.e., rooms in item b can be completed prior to rooms in item a:
    a. Dispensing Room side of Dispensing/Prep first followed by Prep side of room and then the Gown Room
    b. WBC Room first followed by WBC Ante
2. Empty all regular trash containers
3. Move pig carts into the Prep side of Dispensing/Prep room when cleaning the Dispensing side of room to facility more thorough cleaning and disinfection.
4. Using a wiper saturated with an approved one step cleaning/disinfecting agent listed in CASOP 6.4.1 Attachment A, wipe horizontal work and contact surfaces to include the following but not limited to:
    a. Ledges and overhangs on outside surrounds of PECs (not inside PEC surfaces)
    b. Clip boards, plastic sheet covers and any tools hanging on sides of hood surrounds
    c. Tables/counters
    d. Supplies/equipment on tables and counters
    e. Containment box outer surfaces, door, and latch
    f. Cart shelves and handles
    g. Storage racks and storage bins
    h. Inside surfaces of each pass-through box
        i. HEPA pass through and hatch between WBC room and Dispensing are wiped as part of the WBC room cleaning
    i. Pass-through box surfaces/handle in clean room environment
    j. Wall phones
    k. Wall mounted hand scrub/sanitizer dispensers
    l. Stool touch surfaces
    m. All door handles and push plates
    n. Hand hygiene sink surfaces including countertop, basin, faucet handles, and backsplash if located in the gown room
5. Tacky roll, dry mop or vacuum floor to remove loose debris if needed.
    a. Microfiber floor mops clean dirt and debris as they spread the cleaner/disinfectant agent so this step may not be necessary
6. Wet mop floors with a one-step cleaning/disinfecting agent listed in CASOP 6.4.1 Attachment A.
    a. It is permissible to apply the one-step cleaning/disinfecting agent directly to the floor
7. Replace tacky mat sheets outside the CR at least once daily or as needed if heavily soiled.
8. Clean/disinfect the hand hygiene sink if located outside the clean room environment with an approved one step cleaning/disinfecting agent listed in CASOP 6.4.1 Attachment A.

B. Weekly clean room sink tank cleaning and disinfection

1. Remove and clean portable sink clean and wastewater tanks at least every 7 days. Clean water tank shall be removed and cleaned more often as needed to keep a clean water supply for hand hygiene.
2. Empty and rinse both clean and wastewater tanks thoroughly with fresh tap water.

3. Fill clean and waste tanks with fresh tap water and add 15mls of unscented 5.25% household bleach for each gallon of water in the tank for a concentration of 50 ppm chlorine. **Let tanks sit for a minimum of 2 hours.**
4. Empty bleach water from tanks and rinse thoroughly with fresh tap water. Allow tanks to air dry.
5. When ready to reuse tanks, refill clean water tank with fresh tap water for reuse.
6. Transfer of tanks into the clean room shall be done through the Gown room.
7. Tanks shall be installed into the sink on the clean side of the line of demarcation by a properly garbed employee.
8. Thoroughly wipe outside of tanks with an approved one-step cleaning and disinfecting agent listed in CASOP 6.4.1 attachment A and install in sink for use.

C. Monthly Cleaning/Disinfecting of ISO Class 7 and 8 rooms
1. Each step of the monthly cleaning/disinfecting must be completed on an individual room in a single day
2. Monthly cleaning/disinfecting of different rooms can be completed on different days
3. If multiple rooms are cleaned/disinfected in a single day, the order in which rooms are cleaned/disinfected shall follow this guidance but the listed order need not be strictly followed, i.e., rooms listed in item b can be completed prior to rooms listed in item a:
    a. Dispensing Room first followed by Prep Room then Gown Room
    b. WBC Room first followed by WBC Ante then WBC Stage 1 room (if applicable)
4. All mop and wipe steps outlined in this procedure will be performed twice in accordance with the following:
    a. The first mop and wipe steps completed shall be done using an approved cleaning agent listed in CASOP 6.4.1 Attachment A.
    b. The second mop and wipe steps shall then be repeated using an approved sporicidal agent listed in CASOP 6.4.1 attachment A.
5. Empty all regular trash containers.
6. Move pig carts into the Prep side of the Dispensing/Prep room when cleaning the Dispensing side of the room to facility more thorough cleaning/disinfection.
7. Tacky roll, dry mop or vacuum the ceilings and walls to remove loose debris if needed.
    a. Microfiber mops clean dirt and debris as they spread the cleaner/disinfectant agent so this step may not be necessary.
8. Using approved equipment and materials with the appropriate approved agent for process step being performed, complete the following:
    a. Wet mop the ceiling
    b. Wet mop the walls making sure to include:
        i. All windows and doors
        ii. All wall mounted equipment such as phones, mirrors, hand scrub/sanitizer dispensers, etc.
        iii. All ledges/bumpers on walls, around doors/windows, and at floor coving
        iv. All return air louvres
    c. Wipe the top, sides, all ledges, and overhangs on outside surrounds of PECs- not inside PEC surfaces.
        i. Note: use extreme care when wiping outside edges of PEC surrounds as some edges are very sharp.
    d. Wipe all clip boards, plastic sheet covers and any tools handing on sides of hood surrounds
    e. Clean/disinfect all tables, counters, carts and racks:

i. Remove all items that are removable from each table, cart and rack as it is cleaned/disinfected
ii. Wipe outer surfaces of non-removable equipment such as the containment box, generator shields, etc., in place on tables.
iii. Wipe all surfaces of the table, cart or rack being cleaned/disinfected, including vertical surfaces, non-touch surfaces and wheels.
iv. Empty and wipe the insides and outsides of each storage bin and container prior to refilling and replacing back on cleaned table, cart or rack.
v. Wipe all items before placing back on tables, carts or racks including kit shields, RAM shields, centrifuge shields, dose calibrators located outside the PEC, pens, etc.

f. Wipe inside surfaces of each pass-through box
   i. HEPA pass through and hatch between WBC room and Dispensing are wiped as part of the WBC room cleaning
g. Wipe pass-through box surfaces/handle in clean room environment
h. Wipe all other equipment in the room such as stools, trash bag holders, RAM trash cans, etc., on all surfaces
i. Clean/disinfect the hand hygiene sink surfaces including countertop, outside cabinet, basin, faucet handles, and backsplash if located in the gown room.
j. Wipe door handles and push plates

9. Tacky roll, dry mop or vacuum floor to remove loose debris if needed.
   a. Microfiber floor mops clean dirt and debris as they spread the cleaner/disinfectant agent so this step may not be necessary.
10. Wet mop floors
    a. It is NOT permissible to apply sporicidal agents directly to the floor
11. Clean/disinfect the hand hygiene sink if located outside the clean room environment.

XIII. Training

All employees shall review this procedure prior to initial site demonstration training.

LIST OF ATTACHMENTS

None

DOCUMENT HISTORY		
Version	**Date**	**Brief Description of Change**
1.0	15 Sept 2021	Reorganized procedure- separated out ISO 7&8 cleaning from the main CASOP 6.4.1 into sub-procedure CASOP 6.4.1.2. Include Remediation requirements, reference new form for investigation documentation, adding approved cleaner for residues, Removed Foam Mop Head from use.
1.1	1 Nov 2021	Administrative
1.2	1 Mar 2022	Update to allow for greater flexibility in use of approved agents. Changes made to align with industry best practices and USP compliance.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RLS (USA) INC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1828 Tribute Road Suite A-E

City Sacramento State CA Zip 95815

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 916-648-3334 Website RLS.BIO

Licensing Company Email Sacramento@RLS.BIO

Section 2: Personal Information

First Paul Middle Andrew Last Fleming

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Tribute Road Suite A-E

City Sacramento State CA Zip 95815

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
University of the Pacific School of Pharmacy			09/90 - 05/93
Address	**City**	**State**	**Zip**
751 Brookside Road	Stockton	CA	95211
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name			From - To (MM/YY – MM/YY)
San Joaquin Delta College			09/87 - 05/90
Address	**City**	**State**	**Zip**
5151 Pacific Avenue	Stockton	CA	95207
Diploma/Degree obtained, if any			
None			

School Name			From - To (MM/YY – MM/YY)
Lincoln High School			09/83 - 5-87
Address	**City**	**State**	**Zip**
6844 Alexandria Place	Stockton	CA	95207
Diploma/Degree obtained, if any			
Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/03 - 04/24	[redacted]Killdeer Way	Elk Grove	CA	95758
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
RLS (USA) INC			08/05 - 04/24
Business Address	**City**	**State**	**Zip**
1828 Tribute Road Suite A-E	Sacramento	CA	95815
Phone	**Title**		**Number of Employed Hours**
916-648-3334	Pharmacy Manager		34,560
Description of Duties			
Sterile Compounding, Dispensing, Recordkeeping, Ensuring Regulatory Compliance			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Paul Fleming, **certify that as the designated representative for**

RLS (USA) INC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PF I am at least 21 years of age;
3. PF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Paul, Fleming

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/10/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Fleming

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/10/2024

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of SACRAMENTO

I, AJAY SINGH, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04/10/2024

Date

Subscribed and Sworn to before me this 10 day of APRIL, 2024

Notary Public Signature

AJAY SINGH
Notary Public - California
Sacramento County
Commission # 2438574
My Comm. Expires Feb 17, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site RLS (USA) Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) NA

Physical Address 1828 Tribute Road, Suite A-E

City Sacramento State CA Zip 95815

Mailing Address (if different from physical address) NA

City 916-648-3334 State _____ Zip _____

Telephone _____ Website RLS.BIO

Licensing Company Email Sacramento@rls.bio

Section 2: Personal Information

First Stephen Middle Andrew Last Belcher

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Primera Blvd., Suite 440

City Lake Mary State FL Zip 32746

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of South Alabama		09/82 - 06/88	
Address	**City**	**State**	**Zip**
307 N University Blvd	Mobile	AL	36688
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
McGill - Toolen High		09/78 - 06/82	
Address	**City**	**State**	**Zip**
1501 Old Shell Rd	Mobile	AL	36604
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20 -	[redacted] West St	Mobile	AL	36604
07/06-07/20	[redacted] Delchamps Ave.	Dauphin Island	AL	36528
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
RLS (USA) Inc.			9/22-Present	
Business Address		**City**	**State**	**Zip**
255 Primera Blvd., Suite 440		Lake Mary	FL	32746
Phone	**Title**			
813-285-3065	CEO			
Description of Duties				
Management of RLS (USA) Inc.				

Business Name			From - To (MM/YY – MM/YY)	
KANO Performance			4/19-Present	
Business Address		**City**	**State**	**Zip**
182 Saint Francis St.		Mobile	AL	36602
Phone	**Title**			
251-616-2033	President			
Description of Duties				
Overseeing budgets, staff, and executives and evaluating the success of the company.				

Business Name			From - To (MM/YY – MM/YY)	
Medical Sales and Management Strategies LLC			7/14-Present	
Business Address		**City**	**State**	**Zip**
9425 Private Rd. 166		Theodore	AL	36582
Phone	**Title**			
	Chairman of the Board			
Description of Duties				
Lead the Board and focusing it on strategic matters, oversee business and setting high governance standards. Plays pivotal role in fostering the effectiveness of the Board and individual Directors.				

Business Name			From - To (MM/YY – MM/YY)	
PermaFix Medical S.A.			2/18-2/19	
Business Address		**City**	**State**	**Zip**
Skarbowców 23a, 53-025		Wrocław, Poland		
Phone	**Title**			
48 71 735 7005	CEO			
Description of Duties				
Management of company				

Business Name			From - To (MM/YY – MM/YY)	
Global PET Imaging			7/14-11/15	
Business Address		**City**	**State**	**Zip**
182 Saint Francis St		Mobile	AL	36602
Phone	**Title**			
	CEO			
Description of Duties				
Management of company				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Tricd Isotopes			01/07 - 07/14
Business Address	**City**	**State**	**Zip**
182 Saint Francis St	Mobile	AL	36602
Phone	**Title**		
	SVP		
Description of Duties			
Over all Sales & Marketing efforts			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Stephen Belcher

Print Name (First, ~~Last~~)

Original Signature (electronic, copies or stamps not accepted)

4/11/24

Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of Mobile

I, Stephen Belcher, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/11/24

Date

Subscribed and Sworn to before me this 11 day of April 2024

Notary Public Signature

Notary Public
Alabama State At Large
My Commission Expires 10/26/26

CHERRELL ROSALES NOTARY PUBLIC ALABAMA STATE AT LARGE (Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site RLS (USA) Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1828 Tribute Road, Suite A-E

City Sacramento State CA Zip 95815

Mailing Address (if different from physical address) NA

City _____ State _____ Zip _____

Telephone 916-648-3334 Website RLS.BIO

Licensing Company Email Sacramento@rls.bio

Section 2: Personal Information

First Mannon Middle George Last Bankson, III

Alias(es, nicknames, name changes, etc.) Trey Bankson

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addre[redacted] Primera Blvd. Suite 440

City Lake Mary State FL Zip 32746

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Alabama at Birmingham		07/98 - 03/00	
Address	City	State	Zip
1720 University Blvd.	Birmingham	AL	35294
Diploma/Degree obtained, if any			
MSHA			

School Name		From - To (MM/YY – MM/YY)	
Auburn University		08/90 - 05/95	
Address	City	State	Zip
Auburn University	Auburn	AL	36849
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/21 - present	[redacted]Falls Crest Place	Auburn	AL	36830
06/19 - 07/21	[redacted]Overhill Court	Auburn	AL	36830
05/99 - 06/19	[redacted]Easton Forest Drive	Tallahassee	FL	32317

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
RLS (USA) Inc.			10/22-Present
Business Address	**City**	**State**	**Zip**
255 Primera Blvd. Suite 440	Lake Mary	FL	32746
Phone	**Title**		
813-285-3065	COO		

Description of Duties

Maintain and drive operational results. Provide leadership and strategic vision, bring operational, managerial and administrative procedures, reporting structures and operation control. Drive results, spur growth, increase efficiency.

Business Name			From - To (MM/YY – MM/YY)
Barnes Healthcare Services			9/15-9/16
Business Address	**City**	**State**	**Zip**
200 S. Patterson St.	Valdosta	GA	31601
Phone	**Title**		
229-245-6001	VP of Pharmacy Services		

Description of Duties

Managed all Pharmacy Operations including Home Infusion, Retail, and Specialty Pharmacy Services across the Southeast.

Business Name			From - To (MM/YY – MM/YY)
East Alabama Apothecary Specialty Pharmacy			03/19 - 03/22
Business Address	**City**	**State**	**Zip**
1171 Gatewood Drive	Auburn	AL	36830
Phone	**Title**		
	Pharmacy Manager		

Description of Duties

Responsible for Specialty Infusion Services of East Alabama Healthcare. Specialty Pharmacy, Home Infusion Pharmacy, Outpatient Infusion Center of East Alabama Medical Center, and Oak Park Long Term Care Pharmacy. Initiated new busi

Business Name			From - To (MM/YY – MM/YY)
Pharmerica			01/00 - 03/19
Business Address	**City**	**State**	**Zip**
1950 Commonwealth Lane	Tallahassee	FL	32303
Phone	**Title**		
	Pharmacist		

Description of Duties

Worked within a team to provide pharmaceutical and consulting services to the long-term care, assisted living, sub-acute, and skilled nursing facilities.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Trey Bankson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/11/24

Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of Lee

I, Linda McCluskey, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/11/24

Date

Subscribed and Sworn to before me this 11th day of April, 24.

Linda McCluskey

Notary Public Signature

(Seal)

Exp 12/14/24

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☑ Service Modification*	☐ Nuclear	DEA #: FP9814573
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☑ Non-sterile Compounding
			☑ Sterile Compounding
			☑ Mail-Order Service
	* Current license #: PH 4292		☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☐ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday = Closed	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday = Closed	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays = Closed	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Performance Wellness Pharmacy LLC d/b/a Seven Cells

Physical Address: 600 SE Indian St, Ste 3

City: Stuart State: FL Zip: 34997

Mailing Address (if different from physical address): Same as physical

City: _____ State: _____ Zip: _____

Telephone: 561-467-5333 Toll Free # (NAC 639.708, NRS 639.23286): 800-818-1779

Fax: 561-467-4899 Contact Email: SS@sevencells.com

Website: sevencellspharmacy.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Venus Hensley

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22228

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name:	NV Pharmacist Registration #:
Name: Venus Hensley	NV Pharmacist Registration #: 22228
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida
Parent Company (if any): N/A
Corporation/Organization Name: Performance Wellness Pharmacy LLC
Mailing Address: 600 SE Indian St. Ste 3
City: Stuart State: FL Zip: 34997
Telephone: 561-467-5333 Email: SS@sevencellc.com
Contact Person Name: Scott Sharp

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Performance Wellness Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Scott Sharp

Print Name of Authorized Person

→ _____

~~Original signature of Authorized~~ Person (copies or stamps not accepted)

3-28-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott Sharp

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

→ _____

Original signature of Authorized Person (copies or stamps not accepted)

3-28-2024

Date

Board Use Only	Date Received: 4/1/24	Amount: $500-Check 1502

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Purformance Wellness Pharmacy LLC d/b/a Seven Cells

NV Pharmacy or Outsourcing facility license # (if applicable): PH04292

Physical Address: 600 SE Indian St, Ste 3

City: Stuart State: FL Zip: 34997

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 561-467-5333 Toll Free # (NAC 639.708, NRS 639.23286): 800-818-1779

Fax: 561-467-4899 Contact Email: Venus.Hensley@sevencells.com

Website: www.sevencellspharmacy.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Venus Hensley

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22228

Name of Person with direct knowledge of compounding procedures: Venus Hensley

Email of Person with direct knowledge of compounding procedures: Venus.Hensley@sevencells.com

Telephone of Person with direct knowledge of compounding procedures: 561-309-9899

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☒ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Semaglutide/B12 5 mg/1000mcg/mL and Tirzepatide/B3 30 mg/2mg/mL

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?
Name: Pharmetric Lab
Address: 11880 28th St N Ste 210
City: St Petersburg State: FL Zip: 33716
Telephone: 727-209-5778

7. What is your procedure for visual inspection of compounded sterile products?
Visual inspection is conducted using a LED light inspection box. As a quality inspection step to determine the absence or or inclusion of particulates in compounded sterile preparations and perform release checks for purity and quality. The LED light box has a 2x magnifying glass that allows for close visual inspection and dual Light Kit (one for black UV LED and one for white LED).

8. How often do you perform glove fingertip and medial fill testing?

Every 3 months.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

A Corrective Action Plan is immediately implemented and discussed with the employee and didactic training or retraining is assigned or reassigned to the employee prior to employee performing the failed test again. Employee is not allowed to compound until there is a successful test and employee has completed all training and is deemed fit to return to compounding duties by the Pharmacist-in-Charge.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Initial and annual training program consists of ASHP (American Society of Health System Pharmacists) USP <797> Pharmaceutical Compounding Sterile Preparations and USP <800> Hazardous Drugs-Handling in Healthcare Settings, didactic course completion, Contec's compliant garbing, material handling and cleaning procedures training completion, successful completion of glove fingertip and media-fill tests along with any other supportive continuing educational training related to sterile compounding.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Always use sterile products inside the CAI/CACI

All Cleaning and disinfectant products are cleaned with Pre empt plus dwell time of one minute followed by alcohol dwell time of one minute or until it is dry before being placed in the PEC. All Sterile products are only open, closed, and utilized in the PEC, if they are opened outside of the PEC a black marker is utilized to place an X over it and given a 14 day bud, the X is to notify staff not to use it in the PEC.

a. Sterile Peridox RTU ; b.Sterile TB1-33000 Disinfectant; c. Sterile Easy Reach applicator; d. Sterile 70% sIPA Pour top bottle; e. Sterile Sterisorb ISO-5 dry wipe; f. Pre empt Plus (non sterile) disinfectant; g. Peridox RTU non sterile; h. Non Sterile 70% sIPA

Please see attached.

12. Who performs the sterile compounding process at your facility?

Sterile compounding is performed by the Certified Compounded Sterile Preparation Technician (CSPT) alongside with and with the oversight of the sterile compounding trained pharmacist.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The pharmacist-in-charge, Venus Hensley.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

We have a detailed written standard operating procedure on point regarding shipping of prescriptions (SOP 1.018) to ensure products are shipped and tracked via FedEx 2-day in insulated packaging with cold packs as needed.

Please see SOP 1.018 and SOP 1.018.1 attached.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

Semaglutide/B12 5 MG/1000mcg/mL and Tirzepatide/B3 30 mg/2mg/mL

2. What sterilization methods are utilized at your facility?

Filter sterilization usin a .22 micron filter followed by sterility and endotoxin batch release testing completed by Pharmetric Lab prior to any patient dispensing and bubble point testing of filter used.

3. Does your facility utilize biological indicators? ☐ Yes ■ No

4. If yes, describe how they are utilized:

N/A

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Venus Hensley

Name of Person who Completed the Form

PIC

Title

VHensley

Signature (copies or stamps not accepted)

3-15-2024

Date

Board Use Only	Date Received: 3/19/24 Date Approved: _____ Approved By: _____

Florida HEALTH Department of Health

PURFORMANCE WELLNESS PHARMACY LLC Seven Cells Pharmacy

License Number: PH34992

Data As Of 2/19/2024

Profession	Pharmacy
License	PH34992
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2025
License Original Issue Date	02/16/2024
Address of Record	600 SE INDIAN ST STE 3 STUART, FL 34997
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

Nevada Sterile Compounding Supplement

Question #11

The procedure for cleaning PEC and SEC are as follows (Compounding isn't performed during Cleaning)
PEC
DAILY
PEC- inside of the PEC using an easy reach tool with sterile easy reach applicator apply Sterile TB1-33000 Disinfectant lightly to the pad clean the top of the Pec(**dwell time of one minute**) in a unidirectional overlapping movement from left to right starting from cleanest (back) to dirtiest (front), next clean the sides of the PEC from cleanest (back) to dirtiest (front) in a unidirectional overlapping movement where your movement is from the top to the bottom working your way towards the front of the PEC you repeat this on the other side of the then proceed to clean the bar, hooks, any and all equipment in the Pec by using the sterile easy reach applicator or the sterile sterisorb ISO 5 dry wipes. Finally the Designated Compounding Area is cleaned in a unidirectional overlapping movement from left to right starting from cleanest (back) to dirtiest (front). If at any time your easy reach applicator becomes dry rewet it with Sterile TB1-33000 Disinfectant. Once done place the Sterile Easy Reach applicator in a ziploc bag for vapor containment.

2.inside of the PEC using an easy reach tool with sterile easy reach applicator apply Sterile 70% sIPA pour lightly to the pad clean the top of the Pec(**dwell time of one minute**) in a unidirectional overlapping movement from left to right starting from cleanest (back) to dirtiest (front), next clean the sides of the PEC from cleanest (back) to dirtiest (front) in a unidirectional overlapping movement where your movement is from the top to the bottom working your way towards the front of the PEC you repeat this on the other side of the then proceed to clean the bar, hooks, any and all equipment in the Pec by using the sterile easy reach applicator or the sterile sterisorb ISO 5 dry wipes. Finally the Designated Compounding Area is cleaned in a unidirectional overlapping movement from left to right starting from cleanest (back) to dirtiest (front). If at any time your easy reach applicator becomes dry, rewet it with Sterile 70% sIPA . Once done place the Sterile Easy Reach applicator in a ziploc bag for vapor containment.

WEEKLY
3..inside of the PEC using an easy reach tool with sterile easy reach applicator apply **Sterile Peridox RTU** pour lightly to the pad clean the top of the Pec(**dwell time of THREE minute**) in a unidirectional overlapping movement from left to right starting from cleanest (back) to dirtiest (front), next clean the sides of the PEC from cleanest (back) to dirtiest (front) in a unidirectional overlapping movement where your movement is from the top to the bottom working your way towards the front of the PEC you repeat this on the other side of the then proceed to clean the bar, hooks, any and all equipment in the Pec by using the sterile easy reach applicator or the sterile sterisorb ISO 5 dry wipes. Finally the Designated Compounding Area is cleaned in a unidirectional overlapping movement from left to right starting from cleanest (back) to dirtiest (front). If at any time your easy reach applicator becomes dry, rewet it with Sterile Peridox RTU. **Once done place the Sterile Easy Reach applicator in a ziploc bag for vapor containment**.REPEAT steps 1-2 utilizing new Sterile Easy Reach applicators. Once done place the Sterile Easy Reach applicator in a ziploc bag for vapor containment.

4.. BUFFER ROOM
Floors are cleaned with Pre empt Plus Disinfectant (**dwell time of one minute**) lightly pour on the microcinch mop pad clean the floor in a unidirectional overlapping movement from left to right starting from cleanest (furthest point away from the door) to dirtiest (to the door).Room is to remain empty for the complete dwell time of one minute from start to finish.

SEC
MONTHLY
Ceiling, Wall, PEC, Carts, Equipment
a. Peridox RTU non sterile
b.Preempt Plus (non sterile) disinfectant
c.Non Sterile 70% sIPA

c.Klean Max Sterile Mop pad

(all steps below repeated 3 times with appropriate agents)

Cleans the irregular surfaces of each area to be cleaned (e.g., ceiling, walls, etc.) that need to be cleaned manually before cleaning flat surfaces of that surface using mop or cleaning tool. Irregular surfaces in rooms include but are not limited to return grilles, handles, door frames, clocks, switch plates, electrical outlets, thermostats, etc.).

Cleans and disinfects the inside surfaces of pass-throughs.

Cleans and disinfects all outside surfaces of the PECs.

Cleans all buffer, ante-room or SCA furniture (carts, shelving, chairs, stools, etc.) beginning with the top and working down to the wheels.

Cleans all vertical and horizontal surfaces including underside of shelves and feet or wheels.

Uses fresh wipes and mop heads/mop head covers as needed throughout the cleaning process changing if they become visibly dirty.

Rewets wipe, tool cover or mop head, mop head cover to ensure that all surfaces being cleaned and disinfected are uniformly wet enough to achieve the dwell time specified.

Cleans floors in the buffer room, ante-room and/or inside the perimeter line of the SCA using dedicated equipment (or in the direction of cleanest to dirtiest such as buffer room to ante-room) with the agents designated in the SOP starting on the wall opposite the room entry door. Moves from farthest area of buffer room to ante-room and out of dirty side of ante-room or from furthest location inside the perimeter line of the SCA to the closest section of the SCA.

SOP No. 1.018

Title of SOP: Shipping of Prescriptions

Original: Yes __ No __ Revision: Yes __ No __ Revision No.: _____

Responsibility:
The pharmacist-in-charge is responsible for this procedure.

Purpose:
The purpose of this standard operating procedure is to ensure that prescriptions requiring shipment are done so safely and properly, and are shipped to the right patient. **Instructions must be provided to the patient on how to contact the pharmacist for patient counseling. Also, the toll free telephone number must be provided to all patients for their communication, free of charge, with the pharmacy and pharmacist.**

Equipment/Supplies Required:

- Appropriate packaging supplies as needed (e.g., cushioned envelope, small boxes, packaging paper, bubble wrap)
  - Computer system to include printer
  - Courier company's contact information
  - Designated bin/area set up appropriately for prescriptions to be shipped
- Ice packs (for possible storage and/or shipping of temperature sensitive meds) when needed
  - Patient's information (address, phone number)
  - Shipping labels
  - Shipping Log (or similar system to track shipments)
  - Written prescription

Procedure:

Courier Company

1. Select a courier company to be used when prescriptions are shipped. US Postal Service Priority Mail (2-3 business days delivery) with tracking is the standard method of shipping. If a patient requests expedited shipping, then overnight shipping.
2. Assign an employee the responsibility of taking daily patients' prescriptions to the courier's office, if the courier does not offer pickup service.

Data entry

1. Enter a note into the computer system in a designated field that specifies the prescription was shipped to the patient. ***Note: This should be done when the prescription is originally entered into the computer system. If the computer system does not have a specific field to designate prescription shipping, a field, such as "comments", should be designated for this purpose.***

2. Make sure that the designated field is shown when the prescription label is printed.

3. Handwrite the information regarding prescription shipping on the printed prescription label, if the computer system does not have a field where additional information can be placed. ***CAUTION: The handwritten note must be legible.***

Area Setup

1. Designate a bin/area in the pharmacy where the prescriptions that must be shipped are placed after they are filled and checked.

2. Assign one or more employees to check throughout the day and at least 2 hours prior to the courier pickup time the designated bin/area for prescriptions to be shipped. ***Note: If the courier does not pick up packages at the pharmacy, the assigned personnel must check the area or bin at least two hours before the prescription is taken to the courier's office.***

3. Complete the Shipping Log to ensure promptness and accuracy of prescriptions being shipped.

Prescription Shipping

1. Highlight the note on the printed prescription label that reads that the prescription must be shipped.

2. Perform a final check of the prescription.

3. Place the prescription in the designated bin/area for prescriptions that are awaiting shipment.

4. Check the designated bin/area for prescriptions that are awaiting shipment, as instructed in the Area Setup information.

5. Complete the Shipping Log for prescriptions that are to be shipped (or ensure that the information regarding prescriptions being shipped is tracked in whatever system is in place).

6. Complete a shipping label to include the pharmacy's name and address on the label and the patient's name and mailing information, confirming that the shipping label information is correct.

7. Affix the shipping label onto the appropriate shipping container.

8. Tightly close and ensure that the prescription is spill-proof.

9. Place the prescription in the appropriate shipping container, which may include Styrofoam or other temperature-resistant containers if applicable.

10. Add ice packs if applicable. Shipping containers are clearly marked "perishable" in order to alert recipients to refrigerate contents immediately upon arrival.

11. Seal the shipping container.

12. Place the contained prescription in the appropriate waiting bin/area, near the Shipping Log.

13. Record on the Shipping Log the time the prescription was picked up by the courier. ***Note: If the prescription was delivered to the courier's office, record on the Shipping Log the time the prescription left the pharmacy.***

Timing

1. Make sure that shipments of temperature-sensitive items are not shipped over the weekend. The pharmacy does not routinely ship temperature sensitive medication but if it does, caution should be taken that appropriate packaging is provided. ***CAUTION: Exposure to temperature extremes for prolonged periods may have negative results to certain preparations. Use "3M MonitorMark Time Temperature Indicator" strips, if needed.***

2. Make sure that shipments made on Fridays take into account potentially longer delivery times. ***CAUTION: Shipments made on Fridays stand the chance of not being delivered until after the weekend.***

3. Immediately upon receipt and review of a prescription for a medication for an acute illness, the pharmacy will advise patient of the standard delivery times and offer the option for expedited shipping or a transfer of the prescription to a local pharmacy at the patient's choice.

Confirmation

1. Notify the patient when they may expect their prescription.

2. Request that the patient notify the pharmacy if the prescription is not received at the expected time.

3. If the prescription being shipped includes a controlled substance (the Pharmacy does not routinely ship controlled substances), the shipping instructions must require than an adult receive the shipment (unless Patient expressly requests that prescription be left for him/her without signature required at a designated address).

4. If the prescription being shipped is for a minor, address the prescription package shipped to the minor's parent unless the minor's parent requests otherwise.

Delays and Non availability of Medication

1. If shipment or delivery of a medication of the medication will be delayed for any reason, the pharmacy will contact the patient to advise of the delay and expected extended delivery date.

1. If the pharmacy is advised that the patient's medication did not arrive at its intended destination within the standard delivery times, the pharmacist on duty shall review the patient's profile and shipping information to track the medication package and advise of expected delivery time. The pharmacist will exercise his/her professional judgment regarding advising patient and timely provision of interim dosage should the patient require interim dosage until the mailed medication becomes available.

SOP No. 1.018.1

Title of SOP: Shipment Timeliness Quality Control

Original: Yes __ No __ Revision: Yes __ No __ Rev. No. ____

Responsibility:

This procedure is the responsibility of the Pharmacist-in-Charge.

Purpose:

The purpose of this procedure is to address the timeliness of shipping, shipping errors, turnaround time and lost shipments.

Equipment/Supplies Required:
Reliable transportation/shipping company.
Software to track shipments.
Proper packaging materials.

Procedures:
1. Prepare procedures for the shipping, tracking, notification and "confirmation of receipt" of medications to patients.
2. Ship preparations in sufficient time that will receive it prior to the date/time of administration.
3. Implement a procedure for tracking the preparation(s) from the point of departure until the time of receipt by the patient or responsible person.
4. Notify the patient if the shipment will be delayed.
5. Notify the patient of any concerns related to weather or other adverse event that might adversely impact the stability and delivery of the medication.
6. Ensure that the patient has a continuous supply of medication if shipment is delayed or lost.

State of Florida
Department of State

I certify from the records of this office that PURFORMANCE WELLNESS PHARMACY LLC is a limited liability company organized under the laws of the State of Florida, filed on October 10, 2019.

The document number of this limited liability company is L19000245902.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023, that its most recent annual report was filed on February 13, 2023, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourth day of October, 2023



Secretary of State

Tracking Number: 9684837785CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

www.FloridaHealth.gov

File # 29703
Insp # 196599

NAME	PERMIT NUMBER	DATE OF INSPECTION
PURFORMANCE WELLNESS PHARMACY LLC		02/15/2024
DOING BUSINESS AS		
SEVEN CELLS PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
600 SE INDIAN ST STE 3	561-467-5333	
CITY	**COUNTY**	**STATE/ZIP**
STUART	MARTIN	FL/34997

Additional Information

Business Operation Hours

M-T-W-TH-F N	Weekly Hours 830-5
Monday N	Monday Hours
Tuesday N	Tuesday Hours
Wednesday N	Wednesday Hours
Thursday N	Thursday Hours
Friday N	Friday Hours
Saturday N	Saturday Hours closed
Sunday Y	Sunday Hours closed

Registered Pharmacist / Intern / Tech

License # PS45985	Licensee Name Venus Hensley
License Type Registered Pharmacists	
License # RPT10176 .	Licensee Name Malissa Patterson
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FP9814573	

License Relations

Pharmacy Affiliate

SHARP, SCOTT	License #

RX DPT MGR/COR/POR

HENSLEY, VENUS LOUISE	License # 45985

Special Sterile Compounding

PURFORMANCE WELLNESS PHARMACY LLC	License # 32888

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs] *No compounding at this time however facility plans to compound eye drops.*	Yes

2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
5. Medium Risk CSP's, in absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	Yes
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *No CSP's compounded at time of inspection.*	N/A
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *No CSP's compounded at time of inspection.*	N/A
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *No CSP's compounded at time of inspection.*	N/A
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *No CSP's compounded at time of inspection.*	N/A
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	N/A
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat] *This has not been completed at time of inspection.*	No
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *No CSP's compounded at time of inspection.*	N/A

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and eppropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	

27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media end Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken end documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressuras are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs] *Documentation missing dates(electronic in Chart), able to review by date.*	Yes
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	Yes
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	Yes
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	Yes
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs] *No drugs onsite at this time*	N/A
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	Yes
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	Yes
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs] *yellow bins*	Yes

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *ATC December 2023* *3 people in room when certification including smoke study completed.* *ante room ISO7, ACPH 47, pass particles, pass leak* *Prep room ISO8, ACPH 32, pass particles, pass leak* *buffer room ISO7, ACPH 38, pass particles, pass leak* *HD prep room ISO8, ACPH 33, pass particles, pass leak* *HD buffer room ISO7, ACPH 48, pass pressure currently however greater than USP 797 2022 version, pass particles, pass leak* *January 8, 2024* *HD prep room has a powder hood that is not ISO certified.* *HD buffer has a CACI ante chamber is ISO7 and main chamber is ISO5 and is externally vented.* *Non HD prep room has powder hood that is not ISO certified.* *Non HD buffer room has a Nuaire CAI is ISO5, and Class 1 powder hood (compounding safety enclosure) and is not ISO certified.*	Yes
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Smoke studies completed on rooms and hoods. Reviewed report. Air returns are in the ceilings of all the rooms. Report states turbulent airflow in rooms except in buffer room there is "Airflow below the work plane is mostly lazy and low speed at locations below the HEPA filters and close to the door". Slow and stagnant flow around the isolator and between the isolator and germfree flow hood.* *Certifier concludes the the air current form HVAC, differential pressures, and air movement by the hoods help to maintain a dynamic turbulent flow in MOST areas of the compounding suite. Equipment operation contributes to keeping the air moving.* *Pharmacy personnel should consider the smoke study when planning and use of the compounding suite including how many people are allowed in the room, location of equipment, and additional supplies.*	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	Yes
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	Yes
57. Parsonnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *Documentation missing dates(electronic in Chart), able to review each date.*	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Floors have several joints that are unable to determine if sealed. Pharmacy manager states they are sealed.* *Modular room with several ledges.* *Doors between all rooms and to main pharmacy are glass swing doors that have large 1plus inch gaps to surrounding area. Concern for microbial ingress.*	Yes
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Solid ceiling*	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	N/A

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *US microfiltrations lab report reviewed of air and surface sampling in December 2023 and January 2024.* *January 2024 collected 8th and not received by lab until the 11th. Samples should be received within 24hours.* *States collection and receipt date however does not specify incubation temperatures or dates incubated.* *4cfu's in HD prep room (non actionable).* *Facility has not started sampling in house at this time.*	No
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media] *TSA used for air sampling. TSA with P and L for surface sampling.* *Since this facility plans to compound high risk/category 2 products the incubation of TSA should be at the 2 different intervals and documented as such.*	No
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period]	Yes
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Surface sampling has been completed 1 time since December 2023. Facility is not compounding at this time but per USP 797 2022 version plans to complete monthly surface sampling.*	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *Facility has only completed 1 sampling so trending not yet available.*	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	N/A
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *On days used, currently not compounding.*	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *No compounding during inspection*	N/A

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes

90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Purell with 85% ethyl alcohol*	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs] *After media fill GFT and surface sample completed per USP<797> 2022.*	Yes
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *High Risk media fill/Category 2 must be completed prior to compounding since facility plans to compound Category 2.*	No
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *High Risk media fill/Category 2 must be completed prior to compounding since facility plans to compound Category 2.* *Technician has training in sterile compounding, sterile to sterile.*	No
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Tacy medical did training and assessments, technician explained cleaning procedures in detail.*	Yes
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *3XGFT completed and after media fill GFT and surface sample completed per USP<797> 2022.*	Yes
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	N/A

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] *Sample label reviewed*	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] *N/A No CSP's compounded at time of inspection. Compounding document has this information.*	N/A
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] *N/A No CSP's compounded at time of inspection. Compounding document has this information.*	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates] *N/A No CSP's compounded at time of inspection.*	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	N/A
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	Yes

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes

112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)] *No CSP's compounded at time of inspection. Compounding document has space for required information.*	N/A
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

LYOPHILIZATION

135. Sterile products prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
136. A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
137.The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
138. The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
139. Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
140. Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
141. Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
142. The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
143.SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment quelification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
144. The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
145. Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	

146. Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin.[64B16-27.797(5) F.A.C.]	
147. Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
148. In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product.[64B16-27.797(5) F.A.C.]	
149. A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
150. Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
151. Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
152. Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
153. Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
154. Potency, radiochemical purity or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

CORRECTIVE ACTION PLAN

155. A corrective action plan is required to be submitted within 30 days for the non-compliant items listed above.	No

Remarks:

Not currently compounding, Initial inspection.
Inspection completed by Swanlee Grubb and Gillian Staikos with Venus Hensley, Malissa Patterson

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature:

GRUBB, SWANIEE

Date:2/15/2024

Representative:

Venus Hensley

Date:2/15/2024

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 27139
Insp # 185844

NAME	PERMIT NUMBER	DATE OF INSPECTION
Purformance Wellness Pharmacy LLC	32888	08/08/2023
DOING BUSINESS AS		
SEVEN CELLS		
STREET ADDRESS	**TELEPHONE #**	**EXT**
600 SE INDIAN STREET STE 3	561-406-3636	
CITY	**COUNTY**	**STATE/ZIP**
STUART	MARTIN	FL/34997

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:00 pm
Monday Y	Tuesday Y
Wednesday Y	Thursday Y
Friday Y	Saturday Y
Sunday N	Saturday Hours CLOSED
Sunday Hours CLOSED	

Registered Pharmacist / Intern / Tech

License # PS45985	Licensee Name Venus Hensley, PDM
License Type Registered Pharmacists	
License # PS40052	Licensee Name Tim Ka-Ming Cheung, Chief Medical Officer
License Type Registered Pharmacists	
License # RPT52189	Licensee Name Steven Lingan
License Type Pharmacy Tech	
License # RPT103264	Licensee Name Edilma Villaman
License Type Pharmacy Tech	
License # 86866	Licensee Name Lisa Michelle Macbeth
License Type Pharmacy Tech	
License # RPT89493	Licensee Name Jessica Zelenke
License Type Pharmacy Tech	
License # RPT96617	Licensee Name Carmen Salgado
License Type Pharmacy Tech	
License # RPT94750	Licensee Name Ashley Jensen
License Type Pharmacy Tech	
License # PS26939	Licensee Name Iershad Oemar
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FP9814573	

License Relations

Pharmacy Affiliate

SHARP, SCOTT	License #

RX DPT MGR/COR/POR

HENSLEY, VENUS LOUISE	License # 45985

Special Sterile Compounding

PURFORMANCE WELLNESS PHARMACY LLC	License # 33445

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.]	Yes
A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.]	N/A
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C]	Yes

Community Requirements General Section

Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	Yes
Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.].	Yes
Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.]	Yes
Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.] *Provided from 5-11-23-reverse distributor is Rx Reverse Distributors Inc.*	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes

Additional Community Requirements

Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.]	Yes
Pharmacist on duty when Rx department open: [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.]	N/A
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.] *See policy binder*	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]	Yes
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	Yes
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality-Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.] *7/20/23, 5/17/23, 1/23/23, 12/30/22, 8/11/22*	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	Yes
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.] *Patient profiles reviewed in Prime Rx*	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.] *Mostly e-prescribed. Please advise prescribers to document the strength of Oxyfocin powder in the notes field example rx158949-this was clarified by a pharmacist.*	Yes
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11] *CII's are not separated from CIII-CV's. Inventory was taken at the open of business day on 1/4/23.*	No
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)] *DEA 222 forms*	Yes
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	Yes

INV359 - Community Requirements

Insp # 185844 | Performance Wellness Pharmacy LLC | File # 27139

Compounding records properly maintained. [64B16-28.140(4), F.A.C.] *At time of inspection, noted non-sterile compounding-pharmacy is compounding capsules, troches, creams, topical hair solution and oral powders (7 cells 7 minutes sachels).*	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.] *Main wholesaler: HD smith, secondary wholesalers: Medisca, Anda, Masters, Parmed, Republic, Second Source, Willow Birch, Darmerica*	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]	N/A
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.]	N/A
Pharmacist has a written collaborative practice agreement. [465.1865, F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent. *Reviewed SOP 1.018*	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The originating pharmacy is identified with pharmacy name and address on the prescription container label.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

Inspection conducted with Venus Hensley

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CULLIPHER, MALA

Date:8/8/2023

Representative:

Venus Hensley

Date:8/8/2023

AC#1428148

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/19/2023	PH 32888	135676

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

QUALIFICATION(S)
Schedule II & III
Community Pharmacy

Expiration Date: FEBRUARY 28, 2025

PURFORMANCE WELLNESS PHARMACY LLC
Seven Cells
600 SE INDIAN STREET
STE 3
STUART, FL - 34997

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

Department of Health

License Verification

FLHealthSource.gov Public Data Portal New Licensed Health Care Practitioners

Printer Friendly Version

Purformance Wellness Pharmacy LLC Seven Cells

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License Number: PH32888

Data As Of 3/28/2024

Site Help

License Information | Secondary Locations | Discipline/Admin Action | Supervising Practitioners | Subordinate Practitioners

Profession	Pharmacy
License	PH32888
License Status	CLEAR/
Qualifications	Schedule II & III Community Pharmacy
License Expiration Date	2/28/2025
License Original Issue Date	08/26/2020
Address of Record	600 SE INDIAN STREET STE 3 STUART, FL 34997
Discipline on File	No
Public Complaint	No

Back

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Department of Health

License Verification

FLHealthSource.gov Public Data Portal New Licensed Health Care Practitioners

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Purformance Wellness Pharmacy LLC Seven Cells

Search Home

License Number: PH33445

Data As Of 3/28/2024

Site Help

License Information | Secondary Locations | Discipline/Admin Action

Profession	Pharmacy
License	PH33445
License Status	CLOSED/
Qualifications	Schedule II & III
	Special Sterile Compounding
License Expiration Date	2/28/2023
License Original Issue Date	07/02/2021
Address of Record	If further information is needed, please contact the Department of Health at (850) 488-0595.
Discipline on File	No
Public Complaint	No

Back

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DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP9814573	03-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-06-2023

PURFORMANCE WELLNESS PHARMACY LLC
D/B/A SEVEN CELLS
600 SE INDIAN ST
STE 3
STUART, FL 34997

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP9814573	03-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-06-2023

PURFORMANCE WELLNESS PHARMACY LLC
D/B/A SEVEN CELLS
600 SE INDIAN ST
STE 3
STUART, FL 34997

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA BOARD OF PHARMACY

Purformance Wellness Pharmacy LLC d/b/a Seven's Cells

NON-RESIDENT PHARMACY
SERVICE MODIFICATION APPLICATION

LIST OF CORPORATE OFFICERS/OWNERS

Scott Sharp
CEO

100% ownership interest

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Performance Wellness Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable): 4292

Physical Address: 600 SE Indian St ste 3

City: Stuart State: FL Zip: 34997

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 561-309-9899 Website: www.SevencellsPharmacy.com

Licensing Company Email: Venus.Hensley@Sevencells.com

Section 2: Personal Information

First: Venus Middle: L Last: Hensley

Alias(es, nicknames, name changes, etc.): Venus Willis (maiden)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted] Hawthorne Dr

City: Lake Park State: FL Zip: 33403

Telephone: [redacted] Email: Venus.hensley@sevencells.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Palm Beach Atlantic University			08/2002 – 12/2010
Address	**City**	**State**	**Zip**
901 S Flagler Dr	West Palm Beach	FL	33401
Diploma/Degree obtained, if any			
Doctor of Pharmacy - PharmD			

School Name			From - To (MM/YY – MM/YY)
Palm Beach Gardens High School			08/1998 – 05/2002
Address	**City**	**State**	**Zip**
4245 Holly Dr	Palm Beach Gardens	FL	33410
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2004 – NOW	[redacted] Hawthorne Dr	Lake Park	FL	33403

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Performance Wellness Pharmacy LLC			12/2021 - NOW
Business Address	**City**	**State**	**Zip**
600 SE Indian St ste 3	Stuart	FL	34994
Phone	**Title**	**Number of Employed Hours**	
561-467-5333	PIC	4,400	
Description of Duties			
supervising pharmacy staff, filling + dispensing medications, record keeping, communication w/ medical personnel;			

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			05/2008-12/2021
Business Address	**City**	**State**	**Zip**
1801 Palm Beach Lakes Blvd	West Palm Beach	FL	33409
Phone	**Title**	**Number of Employed Hours**	
561-615-0415	PIC from Intern	24,000	
Description of Duties			
supervising pharmacy staff, filling + dispensing medications, record keeping, communication w/ medical personnel + oversight of all claims			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic copies or stamps not accepted)

3-28-2024
Date

I, Venus L. Hensley, **certify that as the designated representative for** Performance Wellness Pharmacy LLC

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VH I am at least 21 years of age;
3. VH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Venus Hensley
Print Name (First, Last)

→ VHensley
Original Signature (electronic, copies or stamps not accepted)

3-28-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Venus Hensley

Print Name (First, Last)

→ Venus Hensley

Original Signature (electronic, copies or stamps not accepted)

3-28-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Martin

I, Venus Hensley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ Venus Hensley

Original Signature

March 28, 2024

Date

Subscribed and Sworn to before me this 28 day of March 2024

Notary Public Signature

MIREYA RIVERA BURAK
MY COMMISSION # HH 255282
EXPIRES: August 20, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Performance Wellness Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 4292

Physical Address 600 SE Indian St ste 3

City Stuart State FL Zip 34997

Mailing Address (if different from physical address) Same as physical address

City _____ State _____ Zip _____

Telephone 561-467-5333 Website www.sevencellspharmacy.com

Licensing Company Email ss@sevencells.com

Section 2: Personal Information

First Scott Middle R. Last Sharp

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] SE Indian St Ste 3

City Stuart State FL Zip 34997

Telephone [redacted] Email ss@sevencells.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Babson Babson College			09/1986 - 05/1990	
Address		City	State	Zip
150 Great Plain Ave		Wellesley	MA	02457
Diploma/Degree obtained, if any				
BS - Finance + Investments				
School Name			From - To (MM/YY – MM/YY)	
St. Luke's School			09/1980 - 05/1986	
Address		City	State	Zip
377 N. Wilton Rd.		New Canaan	CT	06820
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/21 - present	[redacted] Chester Bay LN	N. Palm Beach	FL	33408
From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/20 - 06/21	Beach Rd	Jupiter Island	FL	33469
From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/20 - 12/20	S. A1A, # 301	Jupiter	FL	33477
From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/13 - 6/20	Rolling Green Rd.	N. Palm Beach	FL	33408
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Performance Wellness Pharmacy LLC Dba Seven Cells			11/19 - present
Business Address	**City**	**State**	**Zip**
600 SE Indian St. Suite 5	Stuart	FL	34997
Phone	**Title**		
561-467-5333	Owner / CEO		
Description of Duties			
Management of sales, Marketing, finance, strategy			

Business Name			From - To (MM/YY – MM/YY)
Reign Living Capital, LLC			02/17 - present
Business Address	**City**	**State**	**Zip**
P.O. Box 30974	Palm Beach Gardens	FL.	33420
Phone	**Title**		
561-914-1888	Managing Member		
Description of Duties			
Development, entitlement and construction of various student housing and residential projects			

Business Name			From - To (MM/YY – MM/YY)
Extreme Speed Motorsports, LLC			10/09 - 11/18
Business Address	**City**	**State**	**Zip**
1862 Martin Luther King Jr. Blvd.	Riviera Beach	FL	33404
Phone	**Title**		
772-388-1690	Owner / CEO		
Description of Duties			
owned and managed a team of 35 people to build, maintain and compete cars in various events, globally.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
08/29/1996		CA		Contra Costa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
SID CA 309977405				
Reason/Charge				
driving under the influence of alcohol				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Scott Sharp				
Name of Business/Industry/Entity				

Provide explanation below:

This event took place so long ago I have very limited recollection and zero records. I have tried to obtain records but they are no longer available. This arrest arose from me driving while under the influence of alcohol. I pled no contest, paid fees, attended driving school. There was no resulting property or injuries and I learned my lesson.

→ _____
Original Signature (electronic, copies or stamps not accepted)

March 28, 2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott Sharp

Print Name (First, Last)

→ _____

Original Signature (electronic, copies or stamps not accepted)

March 28, 204

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Martin

I, Scott Sharp, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ _____

Original Signature

March 28, 2024

Date

Subscribed and Sworn to before me this 28 day of March 2024

_____

Notary Public Signature

MIREYA RIVERA BURAK
MY COMMISSION # HH 255282
EXPIRES: August 20, 2026

(Seal)

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☒ Service Modification* ☑ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH 04076	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FS5331587 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: SNF HOLDINGS LLC dba VIOS COMPOUNDING PHARMACY

Physical Address: 31035 SCHOOLCRAFT RD

City: LIVONIA State: MI Zip: 48150

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 2485305769 Toll Free # (NAC 639.708, NRS 639.23286): 8005189831

Fax: 2485305769 Contact Email: SNFHOLDINGSLLC@GMAIL.COM

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): FAYEZ FARAJ

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22223

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: FAYEZ FARAJ	NV Pharmacist Registration #: 22223
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NR5.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: SNF HOLDINGS LLC

Mailing Address: 31035 SCHOOLCRAFT RD

City: LIVONIA State: MI Zip: 48150

Telephone: 2485305769 Email: SNFHOLDINGSLLC@GMAIL.COM

Contact Person Name: FAYEZ FARAJ

Please check type of partnership (NAC 639.214) ☑ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☑ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the MEMBER/PIC (title) for SNF HOLDINGS LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

FAYEZ FARAJ

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

04/08/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

FAYEZ FARAJ

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

04/08/2024

Date

Board Use Only	Date Received: 4/11/24	Amount: $500-cc

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: SNF HOLDINGS LLC

NV Pharmacy or Outsourcing facility license # (if applicable): PH04076

Physical Address: 31035 SCHOOLCRAFT RD

City: LIVONIA State: MI Zip: 48150

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 2485305769 Toll Free # (NAC 639.708, NRS 639.23286): 8005189831

Fax: 2483082635 Contact Email: SNFHOLDINGSLLC@GMAIL.COM

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): FAYEZ FARAJ

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22223

Name of Person with direct knowledge of compounding procedures: FAYEZ FARAJ

Email of Person with direct knowledge of compounding procedures: SNFHOLDINGSLLC@GMAIL.COM

Telephone of Person with direct knowledge of compounding procedures: 3133771321

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☒ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Testosterone cypionate
Tri-testosterone (testosterone cypionate, propionate, and enanthate)
Testosterone cypionate with anastrozole
Testosterone enanthate

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?
Name: PHARMETRIC LAB
Address: 11880 28th St #210
City: St. Petersburg State: FL Zip: 33716
Telephone: 7272095778

7. What is your procedure for visual inspection of compounded sterile products?
Finished CSPs are individually inspected. Immediately after compounding, and as a condition of release, each CSP unit, is inspected against lighted white and black background for evidence of visible particulates or other foreign matter. Prerelease inspection also includes container–closure integrity and any other apparent visual defect. CSPs with observed defects are immediately discarded or marked and segregated.

8. How often do you perform glove fingertip and medial fill testing?
EVERY 6 MONTHS

9. What is your policy if an employee fails a glove fingertip or media-fill test?
Failure of any of the 3 initial garbing competency evaluations requires repeat testing until personnel successfully completes 3 evaluations in a row.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Garbing competency evaluations include: 1. Visual observation 2.Gloved fingertip and thumb sampling (GFT) of both hands. (must complete an initial garbing competency evaluation no fewer than 3 separate times. The 3 successful completions must be in succession)
Aseptic manipulation evaluations include: 1. Visual observation 2. Media-fill testing with post-GFT 3. Surface sampling
Must complete 1 successful aseptic manipulation competency evaluation
Every 6 months all of the above is re-tested.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Cleaning is performed daily, before batch, after batch, in between batches, weekly and monthly. The cleaning sequence will be from the cleanest environment progressing to the dirtiest. The LAFWBs and BSCs will be cleaned first, then manufacturing room B and A, then ante-area, and then non-classes such as prep room and shipping
room. When cleaning the rooms start from the location farthest from the entrance into the room and work toward the exit to avoid walking over cleaned areas.
1. Daily cleaning of PEC and SEC are cleaned with a cleaning agent TB-1 and sterile IPA 70% from Contec. Sterile IPA 70% is used consistently for cleaning throughout the compouding day to maintain cleanliness. Daily Clean/Sanitize the inside surfaces of ISO Class 5 PECs. Clean sanitize counters, work surfaces, equipment, pass throughs, floors.
2. Same as daily including cleaning/sanitize walls.
3. Monthly same as weekly including ceilings. A sporicidail agent is used for this clean. We use sterile Peridox followed by sterile IPA 70%.
For deactivation and decontamination we use Peridox for both, followed by IPA 70%.

12. Who performs the sterile compounding process at your facility?
Pharmacist- Mohamed Faraj, Fayez Faraj
Technician: Spenser Spivak

13. Who is responsible and accountable for the sterile compounding process at your facility?
Fayez Faraj PIC
Victor Hill Quality Director

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Transportation methods for CSPs should be evaluated, as some forms of transportation may adversely affect stability or integrity. Based on these parameters pharmacy will ship CSP utilizing FedEx, USPS, or UPS. For any refridgrated CSP they will be placed in a cooler box with sufficient ice packs and shipped overnight. Proper packaging must be chosen to prevent contamination, leaks, damage, and temperature variations and to protect the end recipients and transporting personnel from harm.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? BSC Class 2 B 2 Laminar Flow Hood		
2. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☑ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☑ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☑ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☑ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? All containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings Labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category. Patients are provided with instruction to contact pharmacy if they have any questions or concerns, or if there has been breakage or leakage of a hazardous drug product. All hazardous drug products are labeled or place in identifying containers that state hazarous drug product.		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Overview of entity's list of HDs and their risks Proper disposal of HDs and trace-contaminated materials Proper use of equipment and devices (eg, engineering controls) Proper use of PPE Response to known or suspected HD exposure Review of the entity's SOPs regarding handling of HDs Proper cleaning methods (deactivation, decontamination and clean/disinfect) Spill management		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
na

2. What sterilization methods are utilized at your facility?
Steam Sterilization (autoclave)
Heat Sterilization (dry heat oven)

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:
Biological Indicators are utilized to validate the autoclave,

The indicator is placed in the most challenging location to sterilize. After the biological indicator is incubated and evaluated for growth.
These are used for routine monitoring of our sterilization process, during validation of equipment, during process validation, and with each batch terminally sterilized.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

FAYEZ FARAJ
Name of Person who Completed the Form

MEMBER/PIC
Title

Signature (copies or stamps not accepted)

04092024
Date

Board Use Only	Date Received: 4/11/24 Date Approved: _____ Approved By: _____

5301012340APP20

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

SNF HOLDINGS, LLC
DBA - VIOS COMPOUNDING
31035 SCHOOLCRAFT RD
LIVONIA, MI 48150

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
PHARMACY LICENSE

STERILE COMPOUNDING

SNF HOLDINGS, LLC
DBA - VIOS COMPOUNDING
31035 SCHOOLCRAFT RD
LIVONIA, MI 48150

LICENSE NO.
5301012340

EXPIRATION DATE
04/07/2026

24086140308

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS5331587	02-28-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-03-2024

SNF HOLDINGS LLC
DBA VIOS COMPOUNDING PHARMACY
31035 SCHOOLCRAFT RD
LIVONIA, MI 48150

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

U.S. Department of Justice
REPORT
CHANGES
PROMPTLY
Drug Enforcement Administration

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

GRETCHEN WHITMER
GOVERNOR

MARLON I. BROWN, DPA
DIRECTOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

VERIFICATION OF LICENSURE

MICHIGAN BOARD OF PHARMACY

VERIFICATION OF LICENSURE AS OF 04/03/2024

NAME: **SNF Holdings, LLC**
ADDRESS: 31035 Schoolcraft Rd
Livonia, MI 48150

STATUS: Active

LICENSE TYPE: Pharmacy License

LICENSE NUMBER: 5301012340

ORIGINAL DATE: 04/07/2020
EXPIRATION DATE: 04/07/2026
SPECIALTY:
None

EXAM DATE	EXAM TYPE	EXAM RESULTS
	None	

OPEN FORMAL COMPLAINTS

No

DISCIPLINARY ACTION	START DATE	END DATE
None		



Brian DeBano, Division Director
Bureau of Professional Licensing
Licensing Division
(517) 241-0199



UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

SNF HOLDINGS, LLC

was validly authorized on October 10 , 2013, as a Michigan
DOMESTIC LIMITED LIABILITY COMPANY
and said limited liability company is validly in existence under the laws of this state and has satisfied its annual filing obligations.

This certificate is issued pursuant to the provisions of 1993 PA 23 to attest to the fact that the company is in good standing in Michigan as of this date.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 19th day of April , 2024.

Linda Clegg

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24040430809

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

Parent Company: SNF Holdings LLC

DBA/Trade Name: Vios Compounding Pharmacy

Type: Limited Liability Company

Business Documents

Company

SNF Holdings LLC (limited liability company)

Tax ID: 46-4012487

Ownership

Fayez Faraj (Pharmacist In Charge)

Member

[redacted] Bella Vista Ct

Northville MI 48168

[redacted]

50 percent owned

Sammy Salem

Member

[redacted] Beaver St

Dearborn MI 48128

[redacted]

50 percent owned

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler SNF HOLDINGS LLC

Pharmacy/Wholesaler License # (if applicable) PH04076

Physical Address 31035 SCHOOLCRAFT RD

City LIVONIA State MI Zip 48150

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 8005189831 Website _____

Licensing Company Email SNFHOLDINGSLLC@GMAIL.COM

Section 2: Personal Information

First FAYEZ Middle _____ Last FARAJ

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 31035 SCHOOLCRAFT RD

City LIVONIA State MI Zip 48150

Telephon[redacted] Email SNFHOLDINGSLLC@GMAIL.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
FORDSON HIGH SCHOOL		08/93-05/95	
Address: 13800 Ford RD.	City: DEARBORN	State: MI	Zip: 48126
Diploma/Degree obtained, if any: HIGH SCHOOL			

School Name		From - To (MM/YY – MM/YY)	
WAYNE STATE UNIVERSITY		SEPT 95-MAY 2000	
Address: 259 Mack Ave	City: DETROIT	State: MI	Zip: 48201
Diploma/Degree obtained, if any: BS PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/09-PRESENT	[redacted]BELLA VISTA CT	NORTHVILLE	MI	48168
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
SNF HOLDINGS LLC			06/2015-PRESENT	
Business Address		**City**	**State**	**Zip**
31035 SCHOOLCRAFT RD		LIVONIA	MI	48150
Phone	**Title**		**Number of Employed Hours**	
8005189831	PHARMACIST IN CHARGE		40HRS PER WEEK	

Description of Duties
PHARMACIST IN CHARGE, CHECKING AND VERIFYING THAT ALL RXS ARE DISPENSED AND COMPOUNDED CORRECTLY, ENSURE ALL PHARMACY RULES AND LAWS ARE FOLLOWED ACCORDINGLY, HANDLE QA/QC,

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties
CONT #1: OVERSEE AND HANDLE EVERYDAY RECORD KEEPING, LOGGING, FILING, DEVELOP SOPS, FINANCES, INVENTORY MAINTENANCE (BOTH CONTROLLED AND NON CONTROLLED), SCHEDULE EMPOYEES

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6-4-24
Date

I, FAYEZ FARAJ, **certify that as the designated representative for**

SNF HOLDINGS LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. FF I am at least 21 years of age;
3. FF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. FF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. FF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. FF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. FF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

FAYEZ FARAJ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6. 4. 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

FAYEZ FARAJ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6.4.2024

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Wayne

I, Fayez Faraj, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6.4.24

Date

Subscribed and Sworn to before me this 4th day of June.

Susan Anne Dopke

Notary Public Signature

SUSAN ANNE DOPKE
Notary Public, State of Michigan
County of Oakland
My Commission Expires 10-04-2025
Acting in the County of Wayne

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site SNF HOLDINGS LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04076

Physical Address 31035 SCHOOLCRAFT RD

City LIVONIA State MI Zip 48150

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 8005189831 Website _____

Licensing Company Email SNFHOLDINGSLLC@GMAIL.COM

Section 2: Personal Information

First SAMMY Middle _____ Last SALEM

Alias(es, nickn[redacted]hanges, etc.) _____

Date of Birth [redacted] SSN or ITI[redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]FAIRBROOK ST

City NORTHVILLE State MI Zip 48167

Telephone 3139999499 Email SASPHARMD@HOTMAIL.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
DEARBORN HIGH SCHOOL		09/94-05/98	
Address	**City**	**State**	**Zip**
19501 W OUTER DRIVE	DEARBORN	MI	48124
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
FERRIS STATE PHARMACY SCHOOL		09/2002-05/2005	
Address	**City**	**State**	**Zip**
220 FERRIS DRIVE	BIG RAPIDS	MI	49307
Diploma/Degree obtained, if any			
PharmD in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
NEW MOTOWN PHARMACY			
Business Address	**City**	**State**	**Zip**
20333 CONANT ST	DETROIT	MI	48234
Phone	**Title**		
3138912253	PHARMACIST		
Description of Duties			
VERIFY DISPENSING AND ACCURACY OF RX, ADHERANCE TO RULES AND REGS, DURS, TRAINING, SCHEDULING, TRAINING, BILLING AND RECONCILIATION, SCHEDULING, COUNSELLING, ETC ETC			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SAMMY SALEM

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-4-2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-4-2024

Date

Subscribed and Sworn to before me this 4th day of 2024.

Notary Public Signature

SUSAN ANNE DOPKE
Notary Public, State of Michigan
County of Oakland
My Commission Expires 10-04-2025
Acting in the County of Wayne

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site SNF HOLDINGS LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04076

Physical Address 31035 SCHOOLCRAFT RD

City LIVONIA State MI Zip 48150

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 8005189831 Website _____

Licensing Company Email SNFHOLDINGSLLC@GMAIL.COM

Section 2: Personal Information

First FAYEZ Middle _____ Last FARAJ

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addres[redacted]BELLA VISTA CT

City NORTHVILLE State MI Zip 48168

Telephone [redacted] Email SNFHOLDINGSLLC@GMAIL.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
FORDSON HIGH SCHOOL			08/93-05/95	
Address		City	State	Zip
13800 Ford Rd.		DEARBORN	MI	48126
Diploma/Degree obtained, if any				
HIGH SCHOOL				
School Name			From - To (MM/YY – MM/YY)	
WAYNE STATE UNIVERISTY			Sept 95 - May 2000.	
Address		City	State	Zip
259 Mack Avenue		DETROIT	MI	48201
Diploma/Degree obtained, if any				
BS PHARMACY				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/09-PRESENT	[redacted] BELLA VISTA CT	NORTHVILLE	MI	48168
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SNF HOLDINGS LLC			06/2015-PRESENT
Business Address	**City**	**State**	**Zip**
31035 SCHOOLCRAFT RD	LIVONIA	MI	48150
Phone	**Title**		
8005189831	PHARMACIST		

Description of Duties

PHARMACIST IN CHARGE RESPONSIBLE FOR VERIFYING AND DISPENSING MEDICAITON, FOLLOWING RULES AND LAWS, DUR, SOPS, FORMULA DEVELOPMENT, QA/QC, TRAINING, INVENTORY, SECURITY ETC ETC

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

FAYEZ FARAJ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6.4.2024

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Wayne

I, Fayez Faraj, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6.4.2024

Date

Subscribed and Sworn to before me this 4th day of June.

Susan Anne Dopke

Notary Public Signature

SUSAN ANNE DOPKE
Notary Public, State of Michigan
County of Oakland
My Commission Expires 10-04-2025
Acting in the County of Wayne

(Seal)

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1259083		**Inspection Information**
Legal Business Name:	SNF Holdings LLC	**Conference Call Date:**	3/20/2024
Doing Business As (DBA):	VIOS Compounding Pharmacy	**Start Time: 24-hour format (13:00)**	9:40
Address:	31035 Schoolcraft Road	**End Time: 24-hour format (13:00)**	11:54
City:	Livonia	**Onsite Inspection Date(s):**	3/20/2024 and 3/21/2024
State:	Michigan	**Start Time(s): 24-hour format (13:00)**	3/20/2024- 12:59; 3/21/2024- 9:00
Zip Code:	48150	**End Time(s): 24-hour format (13:00)**	3/20/2024- 17:00; 3/21/2024- 15:05
Telephone number:	248-530-5769	**Inspector Name:**	Howard Kramer RPh
Toll free number:	800-518-9831	**Inspection Performed by (NABP, State, etc):**	NABP
Fax number:	248-308-2635/800-537-5193	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.vioscompounding.com	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The facility is encouraged to read the inspection report in its entirety and carefully.
Specific Module(s) and/or Question(s) to which the facility may want to consider further response are:
General Pharmacy- 24.00, 51.00, 83.00, 91.00, 93.00
Nonsterile - 3.0 - 3.3
Sterile- 2.0, 2.1, 44.5, 84.0, 85.0, 86.0
Hazardous- 8.00, 8.02, 13.04.03, 73.03, 86.00

Additional information on NABP's Inspection website:

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	9:00	18:00	
Tuesday	9:00	18:00	
Wednesday	9:00	18:00	
Thursday	9:00	18:00	
Friday	9:00	18:00	
Saturday	10:00	14:00	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Fayez Faraj	fayez@vioscompounding.com	158792
Nonsterile Compounding Supervisor	Fayez Faraj	fayez@vioscompounding.com	158792
Sterile Compounding Supervisor	Fayez Faraj	fayez@vioscompounding.com	158792
Hazardous Compounding Supervisor	Fayez Faraj	fayez@vioscompounding.com	158792

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Fayez Faraj	PIC/designated person	Y
2	Victor Hill	Quality Director/designated person	N/A
3	Jean Bechard	Technician	Y
4	Miranda Bowen	Technician	Y
5	Heidi Busch	Technician	Y
6	Mohamed Faraz	Pharmacist	Y
7	Razan Mahdi	Technician	Y
8	Cierra Potts	Technician	Y
9	Spenser Spivak	Technician	Y
10	Souzan Zaitouna	Technician	Y

There were no additional personnel present.

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Business Licensure Information for State of Residence and Federal
(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Michigan Board of Pharmacy	SNF Holdings LLC	Pharmacy	5301012340 - 4/7/2024
Michigan Board of Pharmacy	SNF Holdings LLC	Controlled Substance - Pharmacy	5315215623 - 4/7/2024
Drug Enforcement Administration	SNF Holdings LLC	Controlled Substance - Pharmacy	FS5331587 - 2/28/2027

Inspector Notes: Non-resident licenses are held in AK, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SD, TN, TX, UT, VT, VA, WA, WV, WI, and WY. There is no insulin stocked and there was no ReliOn insulin observed. There are no platforms used that are a marketplace for pharmacies to buy, sell, and bid on short-date prescription drugs, and no price labels for any such platforms were observed. A copy of a COA for each of the API providers is attached to this report, please see Doc01_PI. There is no semaglutide compounded. There are no biologicals compounded. There is no white bagging. Fayez Faraj is the designated PIC actively licensed in Texas (Texas license 61552) and onsite 40 hours or more per week.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_PI	COA copy for each API source
Doc02_GP_24.00	FDA inspection, Form 483, deficiencies, and the facility's reponse to the FDA

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Telepharmacy	
Open to the Public	X	Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy		Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	X
HMO/PBM only		Nonsterile Hazardous Drug Compounding	X
Internet Pharmacy (New Rx)		Sterile Compounding	X
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	X

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)	X	CSPs with controlled substance(s)	X
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements	
CNSPs for INDs		CSPs for INDs	
CNSPs which are essential copies of a commercially available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list		CSPs which are essential copies of a commercially available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list	X
CNSPs sold OTC		CSPs sold OTC	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific:		Patient specific:	
CNSPs for animals	X	CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	X
Distributed (eg non patient-specific):		Distributed (eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous	X	Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	X
Specific types:		Category 3 CSPs	
Solid oral preparations	X	Types of CSPs:	
Liquid oral preparations	X	Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations	X	Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Creams	X	Injections including infusions	X
Gels	X	Irrigations for internal body cavities (eg bladder or peritoneal cavity)	
Ointments	X	Ophthalmic dosage forms	
Lotions	X	Aqueous preparations for pulmonary inhalation	
Nasal and sinus preparations:		Baths and soaks for live organs and tissues	
Nasal sprays	X	Implants/ Pellets	
Nasal irrigations		Other (please list):	
Other (please list):			

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Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	6,000	Total Pharmacists:	2
Nonsterile Compounding Room size:	300	Number of Compounding Pharmacists	2
Nonsterile Compounding powder hoods number:	3	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	300	Total Student Interns:	2
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	6	Total Technicians:	10
Sterile Compounding Ante Room size:	100	Number of Compounding Technicians	6
Sterile Compounding Clean/Buffer Room size:	100	Of technicians, how many are certified?	0
Sterile Compounding Number LAFW hoods/areas:	1	Of technicians, how many are techs-in-training?	5
Sterile Compounding Number BSC hoods:	1	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	0	Total Other Unlicensed Personnel:	1
Negative Pressure Sterile HD Room size:	buffer room-120; filler room- 50	Ratio #Tech:#RPh present at time of inspection:	7:2
Sterile HD Compounding Number of BSC hoods:	1- buffer; 1 filler room	Total Pharmacist Hours Per Week:	80
Sterile HD Compounding Number of CACI hoods:	0	Total Technician Hours Per Week:	380

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A, No sample was collected during this inspection.
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	The inspector observed compounding from the anteroom, which afforded excellent observation.

	Volume Dispensed		Volume Distributed
Total Prescriptions Dispensed/day:	150	Total Orders Distributed/day:	0
% Veterinary Prescriptions	<1%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	30%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	98%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	<1%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	50%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)	14	0	January 2024
Arizona (AZ)	69	0	January 2024
Arkansas (AR)	52	0	January 2024
California (CA)	575	0	January 2024
Colorado (CO)	138	0	January 2024
Connecticut (CT)	33	0	January 2024
Delaware (DE)	3	0	January 2024
District of Columbia (DC)			
Florida (FL)	452	0	January 2024
Georgia (GA)	83	0	January 2024
Hawaii (HI)	2	0	January 2024
Idaho (ID)	8	0	January 2024
Illinois (IL)	438	0	January 2024
Indiana (IN)	58	0	January 2024
Iowa (IA)	104	0	January 2024
Kansas (KS)	9	0	January 2024
Kentucky (KY)	14	0	January 2024
Louisiana (LA)	48	0	January 2024
Maine (ME)	20	0	January 2024
Maryland (MD)	56	0	January 2024
Massachusetts (MA)	1	0	January 2024
Michigan (MI)	538	0	January 2024
Minnesota (MN)	38	0	January 2024
Mississippi (MS)	10	0	January 2024
Missouri (MO)	148	0	January 2024
Montana (MT)	10	0	January 2024

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States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	24	0	January 2024
Nevada (NV)	23	0	January 2024
New Hampshire (NH)			
New Jersey (NJ)	79	0	January 2024
New Mexico (NM)	3	0	January 2024
New York (NY)	124	0	January 2024
North Carolina (NC)	138	0	January 2024
North Dakota (ND)			
Ohio (OH)	50	0	January 2024
Oklahoma (OK)	26	0	January 2024
Oregon (OR)	16	0	January 2024
Pennsylvania (PA)	180	0	January 2024
Rhode Island (RI)	1	0	January 2024
South Carolina (SC)			
South Dakota (SD)	1	0	January 2024
Tennessee (TN)	68	0	January 2024
Texas (TX)	383	0	January 2024
Utah (UT)	5	0	January 2024
Vermont (VT)	3	0	January 2024
Virginia (VA)	129	0	January 2024
Washington (WA)	15	0	January 2024
West Virginia (WV)	5	0	January 2024
Wisconsin (WI)	33	0	January 2024
Wyoming (WY)	7	0	January 2024
Other			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy
e-Profile ID: 1259083
Inspection Date: 3/20/2024 & 3/21/2024

	General Pharmacy	Observation	Notes
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	The PIC is onsite about 40 hours per week or more.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	Yes	Refills can be ordered through the website by completing a refill request form on the website. The patient must complete the form with their personal information and the prescription number.
8.00	Are photographs allowed during the inspection (**no PHI**)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Victor Hill, Quality Director/designated person, participated, and Sue Dopke, HR Director, assisted by phone.

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy
e-Profile ID: 1259083
Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy
e-Profile ID: 1259083
Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	All licenses are framed and posted at the front entrance on the wall.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	The Michigan Board of Pharmacy inspected on 2/1/2022. There are no scheduled inspections by the Michigan Board of Pharmacy.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	Lab coats and bonnets for one employee were hung in the lunch room. This has been corrected.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy
e-Profile ID: 1259083
Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	Yes	The FDA inspected the pharmacy from 2/13/2023 to 3/2/2023. A copy of the FDA Form 483, including deficiencies, and the facility response is attached to this report. Please see Doc02_GP_24.00. The FDA does not perform regular inspections at this pharmacy.
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	ACHC accredited the pharmacy for PCAB from a survey dated 3/8/2022.
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	All required records are maintained onsite for a minimum of 5 years, however, all are on file for the past 9 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	All required records are maintained onsite for a minimum of 5 years, however, all are on file for the past 9 years.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	All electronic prescription are maintained electronically.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	All dispensing records are maintained electronically.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	The system allows prescriptions to be deactivated but does not allow prescriptions to be deleted.

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy
e-Profile ID: 1259083
Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	This is a part of the P & P.
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	License information is entered into Comploy, the HR and payroll system when a new employee is hired. The system alerts the HR manager, the PIC, and the employee beginning 90 days in advance of the expiration, and every 30 days after the initial alert. The HR Manager also maintains a spreadsheet of licensing.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	The HR Manager reviews state websites quarterly for verification of licenses.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	N/A	There is no technician ratio in Michigan. The maximum number of employees working at any time is 10 technicians and 2 pharmacists.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The alarm system is an ADT system. There are glass breakage sensors, motion detection devices, and magnetic door sensors. There are two keypads to arm and disarm the system, one at each door. Each pharmacist has a unique PIN to arm and disarm the system. The PIC is notified of any excursion, by phone call, text message, and email. The PIC's business partner (also a pharmacist but not at this pharmacy), and the other VIOS pharmacist are notified if the PIC does not respond to the alert.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	There are no C-II drugs stocked.

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e-Profile ID: 1259083
Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	The PIC would stay on site until security could be restored and may take drugs to his home if necessary to ensure their security.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	There are no drugs destroyed onsite.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Stericycle is the reverse distributor.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Stericycle manages hazardous waste and collects on demand.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	N/A	
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	The CRT area temperature is controlled by a thermostat. The current CRT area temperature is 69 degrees F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Sensor Scientific is the continuous electronic monitoring and recording system for CRT area, refrigerator, and freezer temperatures. Excursions are sent to the PIC by a cell phone alert.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	Compounded products are given a visual review for inconsistencies. APIs and product components are reviewed for stability information, including COAs. Products may be sent out to a lab for testing if necessary.

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e-Profile ID: 1259083
Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Sensor Scientific is the continuous electronic monitoring and recording system for CRT, refrigerator, and freezer temperatures. The refrigerator range is 2 to 8 degrees C. Excursions are sent to the PIC through an alert on his cellphone. Records are maintained infinitely.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	Refrigerator temperatures were as follows: hazardous sterile area- 4.1 degrees C; sterile area- 5.0 degrees C; finished product nonsterile area- 6.3 degrees C; nonsterile hazardous drug storage- 3.2 degrees C.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	There are no frozen pharmaceuticals at this time. The freezer system is set up for use and Sensor Scientific is the continuous electronic monitoring and recording system. Excursions are sent to the PIC as an alert on his cell phone. The range is -25 to -10 degrees C. Records are maintained infinitely.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	Yes	The current freezer temperature is -17.8 degrees C.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	There is an onsite backup generator that operates the entire facility. Multiple refrigerators could be used for refrigerated drugs should one fail.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	A contingency contract is in place for Air King, in Redford, MI. Air King does preventive maintenance quarterly and provides prioritized HVAC service.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	The facility would complete a QC check and review, and may send samples out for potency tests if needed.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The facility can order only from NABP accredited facilities.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	The only wholesaler is McKesson, and NABP accredited supplier. Other sources for APIs are Fagron, PCCA, and Medisca.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	The pharmacy uses only NABP accredited facilities.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	Yes	The pharmacy uses only NABP accredited facilities.
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	The pharmacy uses only NABP accredited facilities.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Yes	The pharmacy uses only NABP accredited facilities.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	The product is quarantined, and the source is contacted for an investigation.

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Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy
e-Profile ID: 1259083
Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	The pharmacy purchases products only from McKesson and the transaction data is on the website when the products are received.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	There are no C-II products.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	There are no C-II products.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	There are no C-II products.
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	No	All controlled substance invoices were properly signed and dated, however, some items had a checkmark by the quantity received, some had a checkmark at the top of the invoice, and most quantities received were not circled.
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	

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		Observation	Notes
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	There is a perpetual inventory system for all drugs and APIs. The CFO reviews P & L statements monthly and advises the PIC if any area appears to be an issue.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	The local authorities are contacted, as well as the board of pharmacy and DEA if appropriate.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	There are no C-II products.
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	There are no C-II products.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	The most recent controlled substance inventory was dated 6/5/2023. The complete CS inventory is performed annually to satisfy Michigan's regulatory requirements.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	

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		Observation	Notes
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Stock is reviewed monthly for outdated products. There are no OTC drugs stocked. Short dated stock is pulled 30 days in advance of the expiration.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Stock is reviewed monthly for outdated products. There are no OTC drugs stocked.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	N/A	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	

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		Observation	Notes
	Prescription Processing If any part of a question is no, enter "No" and explain the observation.		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Data may be entered by a technician or a pharmacist. Data is updated as necessary with every patient contact, which occurs with every prescription filled.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	The system has a box to indicate a veterinary prescription, which provides a drop-down box for the species name.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	Staff is aware of red flags to fraudulent prescriptions. The prescriber is contacted if necessary, and may also be investigated using Google maps and other search engines.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	The prescriber and the local police and the board of pharmacy are contacted.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	The staff investigates and speaks with the prescriber if there are questions. The prescriber is investigated to ensure they have a brick-and-mortar facility. The patient is questioned to determine what kind of visit occurred. The practice may be blocked from the system if it is determined there is no valid prescriber-patient relationship.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	The system is for controlled substances and noncontrolled substances.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	A pharmacist verifies all data entry at PV1.

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		Observation	Notes
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR occurs at data input, at PV1 and at PV2.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	There are no other parameters included.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	No	
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	PMP data is accessed if there are questions regarding controlled substance use.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Only pharmacists can override DUR. Overrides are systematically recorded using the pharmacist's logon credentials.

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67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Medispan is the integrated DUR system used.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	No	Drug Compounding for Veterinary Professionals by Wiley is used, and is a hard copy.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	A tech-check-tech occurs first, with the data entry reviewed by another tech. The compounder also verifies the data entry. A pharmacist verifies the final filled prescription by comparing an electronic copy of the original prescription to the final product and label, as well as a copy of the compounding record.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Labels are produced according to the most stringent regulations including California and New York.
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Life File is the pharmacy system used.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	ShredCorp is the shredder used.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	

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		Observation	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	The offer is made by a technician or pharmacist.
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	

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76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	The offer is made by a technician or pharmacist.
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	No	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	Yes	The offer is made by a technician or pharmacist.
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	There are no delivered prescriptions.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Printed counseling information is included with every prescription. A toll-free number is on all printed material sent and on the prescription label. Pharmacists or technicians speak to most patients before the delivery of the prescription.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	PPIs are systematically printed and included in every shipment where required.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	N/A	There are no drugs dispensed requiring MedGuides.

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82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	Yes	Isotretinoin is the only REMS drug.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	No	Patient counseling can be entered into patient notes if the pharmacist feels it is appropriate.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	No	
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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		Observation	Notes
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	The PIC and Victor Hill, Quality Director oversee the program.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	P & P is hard copy and electronic.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	The Quality Director has been employed here for one year. The last review of all employees on CQI was dated 7/6/2023 and will be reviewed again in July 2025
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Documentation is both hard copy and electronic.

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88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	The Quality Director reviews each event and analyzes the data quarterly, with the assistance of the PIC if needed.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	There is no drug formulary used.
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

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90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	No	
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	Yes	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***	[redacted]	LAB-501 Non-sterile Compounding Area Requirements Revision 2.0 Effective 10/25/2023	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***	[redacted]	QC-001 Quality Assurance Revision 2.0, effective 4/10/2023; QC-002 Training Revision 100, Effective 4/7/2023	2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***	[redacted]	LAB-504 Non-sterile Compounding Staff Validation Revision 2.0 Effective 5/3/2023; LAB-502 Non-sterile Compounding Staff Validation Revision 2.0 Effective 5/3/2023	3.3, 11

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		Observation	Inspector Notes	USP Reference(s)
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		LAB-014 Inventory Control Revision 2.0 Effective 2/7/2024	6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		QC-006 Out-of-Specification Revision 2.0 Effective 4/13/2023; LAB-711 Environmental Monitoring Revision 1.0 Effective 5/2/2023	4.2, 11
1.6	**Equipment:** The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		RISK-004 API Failure Mode and Effects Analysis Version 1.0 Effective 3/4/2024	6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		LAB-503 Cleaning and Deactivating Non-Sterile Areas Revision 2.0 Effective 10/16/2023	6.2.5, 11

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National Association of Boards of Pharmacy®
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[redacted] Nonsterile Compounding Inspection for USP <795>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***	[redacted]	LAB-010 Master Formulation and Compounding Records Revision 2.0 Effective 4/17/2023	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***	[redacted]	LAB-006 Labeling of Products Revision 2.0 Effective 4/17/2023	9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***	[redacted]	QC-001 Quality Assurance Revision 2.0 Effective 4/10/2023	11, 12 USP <1163>
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***	[redacted]	QC-020 Adverse Events Revision 2.0 Effective 4/16/2023 ; QC-007 Customer Complaints Revision 2.0 Effective 4/16/2023	1.1.3, 11, 12.1, 12.2, 12.3

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		LAB-003 Shipping Medications Revision 2.0 Effective 2/7/2024	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		LAB-003 Shipping Medications Revision 2.0 Effective 2/7/2024	11, 13.2
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary.*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***		QC-008 Drug Recall Revision 2.0 Effective 4/28/2023	12.1

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Nonsterile Compounding Inspection for USP <795>

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e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** *If no, go to compliance statements.*	Yes		1.1.4
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes		1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4

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		Observation	Inspector Notes	USP Reference(s)
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	No	The Quality Director did not know the PIC/designated person, who approves all SOPs and training, required documentation of the training and an evaluation. Documentation, training, and an evaluation will be scheduled, per the Quality Director.	2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14

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Nonsterile Compounding Inspection for USP <795>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** *If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.*	No		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** *Inspector should complete the <795> Records Review module question 3.0.*	Yes		2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		

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		Observation	Inspector Notes	USP Reference(s)
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	Yes		3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	The temperature is recorded by a continuous monitoring and recording device.	4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes		4.2

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		Observation	Inspector Notes	USP Reference(s)
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes		4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2

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11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		The current temperature is 22.8 degrees C.	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	Yes	Tap water is used for rinsing equipment in the sink, and the equipment is then washed in a commercial dishwasher.	4.3 USP <1231>

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***	[redacted]		5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	Yes		5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components.**	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes	Walls and ceilings are also cleaned and sanitized monthly.	5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes	This is performed monthly.	5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5
	Equipment and Components			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	Yes	A BSC is used.	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes	Balances are calibrated every morning using the self calibration feature.	6.1

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		Observation	Inspector Notes	USP Reference(s)
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes	Balances are calibrated by an outside service annually.	6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the Inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	Yes		6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	Yes		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	Yes		6.2.1

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		Observation	Inspector Notes	USP Reference(s)
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	Yes		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes	Purified water is used.	6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***			6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2

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Nonsterile Compounding Inspection for USP <795>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	Yes		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4

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		Observation	Inspector Notes	USP Reference(s)
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	Yes		6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes	SDS are electronic and available to all employees.	6.2.5

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		Observation	Inspector Notes	USP Reference(s)
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes	The pharmacy uses BUDs as prescribed by the USP Chapter, the supplier of the API or documented studies.	7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
28.3	MFR includes the type of container–closure system(s).	Yes		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes		7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes.***	Yes	The balance provides a print out of all weights. A technician confirms other measurements that are not recorded by the balance. A second technician confirms the measurements and verification of steps. The product goes to QC where a designated person, a QC technician or a pharmacist observes the compound for a visual review and reviews the compounding record. The product is then moved to filling after approval.	2, 7.2, 8

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		Observation	Inspector Notes	USP Reference(s)
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes		9
31.7	The label on the immediate container includes the dosage form.	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A .***	Yes		9
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1

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		Observation	Inspector Notes	USP Reference(s)
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	Yes		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	Yes		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	Yes		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	Yes		10.5
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	Yes		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	Yes		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** *If no, go to compliance statements.* *If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.*	Yes		10.4
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw <u>≥</u> 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** *If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.* *If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.*	Yes		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>

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Nonsterile Compounding Inspection for USP <795>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A	Table 4 BUDs are not exceeded.	10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	N/A		10.5
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	N/A		10.5

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Nonsterile Compounding Inspection for USP <795>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	N/A	There have been no complaints or adverse events.	12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	No		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2

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		Observation	Inspector Notes	USP Reference(s)
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, Inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documented the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes		3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2

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		Observation	Inspector Notes	USP Reference(s)
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Compounding of 4-aminopyridine 5 mg/ml 30 gm cream was observed.	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3

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		Observation	Inspector Notes	USP Reference(s)
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2

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		Observation	Inspector Notes	USP Reference(s)
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation.** Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes		8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9

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Nonsterile Compounding Inspection for USP <795>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5

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e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	PIC	Pharmacist	Technician-B	Technician-S	Technician-R	Notes
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes	Missing	Yes	Missing	Previous records were not available. The training program is new and some personnel have not yet been trained using the new system.
1.2	Compounding personnel are trained on USP <795> standards.	missing	missing	missing	missing	missing	This training was completed on Critical Point. Critical Point removed all system records of previous training with the new Chapter <795>.
1.3	The training record for hand hygiene is complete.	missing	missing	Yes	missing	Yes	
1.4	The training record for garbing is complete.	missing	missing	Yes	missing	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Missing	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting components and CNSPs is complete.	Missing	Yes	Yes	Yes	Yes	

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	Employee Title	PIC	Pharmacist	Technician-B	Technician-S	Technician-R	Notes
1.7	The training record for measuring and mixing is complete.	Missing	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Missing	Missing	Missing	Missing	Missing	There is an evaluation for all five compounders but no documentation of training. The Quality Director stated their evaluation is their training record.
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Missing	Missing	Missing	Missing	Missing	
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Missing	Missing	Missing	Missing	Missing	
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Missing	Missing	Yes	Missing	Yes	
1.12	The training record for spill management is complete.	Missing	Yes	Yes	Yes	Yes	
2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.	Missing	Yes	Yes	Yes	Yes	
2.2	Compounding personnel are re-trained on USP <795> standards.	Missing	Yes	Yes	Yes	Yes	
2.3	The annual competency assessment for hand hygiene is complete.	Missing	Yes	Yes	Yes	Yes	
2.4	The annual competency assessment for garbing is complete.	Missing	Yes	Yes	Yes	Yes	
2.5	The annual competency assessment for cleaning and sanitizing is complete.	Missing	Yes	Yes	Yes	Yes	
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	Missing	Yes	Yes	Yes	Yes	
2.7	The annual competency assessment for measuring and mixing is complete.	Missing	Yes	Yes	Yes	Yes	

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	Employee Title	PIC	Pharmacist	Technician-B	Technician-S	Technician-R	Notes
2.8	The annual competency assessment for proper use of equipment is complete.	Missing	Yes	Yes	Yes	Yes	
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Missing	Yes	Yes	Yes	Yes	
2.10	The annual competency assessment for interpreting a COA is complete.	Missing	Missing	Missing	Missing	Missing	
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	Missing	Missing	Missing	Missing	Missing	
2.12	The annual competency assessment for spill management is complete.	Missing	Yes	Yes	Yes	Yes	
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A. Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	Yes	Yes	Yes	Yes	Yes	

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.

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Glossary & References	USP <795>
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.

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Glossary & References	USP <795>
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba V'OS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)		**Please note NABP did not review each SOP for alignment on USP <797>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."*** ***If no, go to compliance statements.***	Yes		1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18

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		Observation	Inspector Notes	USP Reference(s)
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17

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		Observation	Inspector Notes	USP Reference(s)
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	No		17

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		Observation	Inspector Notes	USP Reference(s)
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).	[redacted]	missing	1.5
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		LAB-702 Cleanroom Staff Validation Revision 1.2 Effective 4/20/2023; REF-LAB-702-A Aseptic Technique Revision 1.0 Effective 4/26/2023; LAB-707 Media Fill Testing Revision Effective 4/14/2023	2, 2.2, 10 Box 1, Box 2, Table 2, Table 3
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***		LAB-704 Cleanroom Garbing Revision 1.1 Effective 4/11/2023	3, 3.3

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		Observation	Inspector Notes	USP Reference(s)
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.	[redacted]	LAB-701 Cleanroom Requirements Revision 1.1, Effective 4/5/2023; LAB-711 Environmental Monitoring Revision 1.0 Effective 5/2/2023	4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.		LAB-711 Environmental Monitoring Revision 1.0 Effective 5/2/2023	5, 5.1
2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.		LAB-711 Environmental Monitoring Revision 1.0 Effective 5/2/2023	6, 6.1, 6.2, 6.3
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		LAB-703 Cleaning and Disinfecting Cleanrooms Revision 3.2 Effective 4/20/2023	7, 7.2 Box 7, Box 8

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		Observation	Inspector Notes	USP Reference(s)
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.		EQUIP-001 Balance Use and Calibration Revision 2.0 Effective 4/2/2023; EQUIP-008 Repeater Pump Use and Calibration Revision 1.0 (not yet effective)	9.1, 10, 20
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.		LAB-014 Inventory Control Revision 2.0 Effective 2/7/2024	9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.		LAB-010 Master Formulation and Compounding Records Revision 2.0 Effective 4/17/2023	11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.		QC-014 Quality Control Revision 1.0 Effective 4/20/2023; QC-006 Out-of-Specification Revision 2.0 Effective 4/13/2023; QC-005 Incidents, Corrective Action, & Preventive Action	12, 18, 20

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.	[redacted]	LAB-006 Labeling of Products Revision 2.0 Effective 4/17/2023	13
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.		LAB-014 Inventory Control Revision 2.0 Effective 2/7/2024	19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***		QC-018 Good Documentation Practices Revision 2.1 Effective 2/7/2024; LAB-010 Master Formulation and Compounding Records Revision 2.0 Effective 4/17/2023	20

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		Observation	Inspector Notes	USP Reference(s)
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***	[redacted]	LAB-705 Sterilization Revision 1.0 Effective 4/26/2023	10
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.3
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.1.2

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2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***	[redacted]	N/A	21
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived			**1**
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use? ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	N/A		1.3
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	N/A		1.3

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4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	N/A		1.3
4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	N/A		1.4
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	N/A		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	N/A		1.4

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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		Observation	Inspector Notes	USP Reference(s)
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only <u>compounds</u> sterile preparations (eg, does <u>not</u> prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	N/A		1.4
6.1	The product is prepared as a single dose for an individual patient.	N/A		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	N/A		1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	No		1.1.2

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	N/A		1.1.2

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
	Facility Design and Engineering Controls			4
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A		4.2.1, 4.2.3 Table 5

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9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	N/A		4.2.1 Glossary

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A		4.5
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1

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9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	N/A		4.2.1, 4.3.2
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops).***	Yes		4.3.2
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).***	Yes		4.2.1, 4.3.2
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	Yes		4.2.1
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes		4.2.1
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1

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12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes		4.1.2, 4.2.1, 4.2.3

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

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12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	N/A	Air returns are located low on the wall, however, a smoke study was performed.	4.2.1
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	Yes		4.2.1

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	Yes	The line of demarcation is a black and yellow taped line.	4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	N/A		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes		4.2.1, 4.3.1

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12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes	Coving is used.	4.2.1, 4.3.1
12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***	Yes		4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes		4.2.2, 4.2.3, 5
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes		4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
13.5	**Category 2 and Category 3**: PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes	Only Category 2 compounds are prepared.	4.2.3 Table 5
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3 Table 5
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** ***If no, go to compliance statements.***	Yes		4.5
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes		4.5

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		Observation	Inspector Notes	USP Reference(s)
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes	Sterile 70% IPA is used.	4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		4, 9.1, 19.1
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	N/A		4.4

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	Yes	The sink is at the opposite end of the anteroom from the buffer room door. There is no garb reused.	4.4
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	This is prevented by training and signage.	4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	This is by interlock.	4.2.1

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected. If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes		4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes		4.2.1
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	Yes		4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	Yes	Carts are designated.	4.5

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***	Yes		4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	Yes		4.2, 9.3.4, 19.1
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	A continuous electronic monitoring and recording system is used.	4.2, 9.3.4, 19.1

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Sterile Compounding Inspection for USP <797>

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18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes	A continuous electronic monitoring and recording system is used.	4.2, 9.3.4, 19.1
18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes	A continuous electronic monitoring and recording system is used.	4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes	A continuous electronic monitoring and recording system is used.	4.2, 9.3.4, 19.1

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb. CRT is defined as 20°C-25°C per USP <659>.***	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	No		4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	N/A		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	[redacted]	The current temperature is 66.2 degrees F.	4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		The current humidity is 51%.	4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	Yes		4.2, 9.3.4, 19.1
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***If no, go to compliance statements.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***	Yes		4.2.1, 4.2.5, 5
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	Yes		4.2.1, 4.2.5, 5

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24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	Yes		4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***	Yes		4.2.1, 4.2.5, 5
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes		4.2.1, 4.2.5, 5

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24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	Yes		4.2.5
27.0	Does the facility perform both sterile and nonsterile compounding?	Yes		4.2.1
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	Yes		4.2.1

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29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	N/A		4.2.1, 4.2.6
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	N/A		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	N/A		4.2.1
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	N/A		4.2.1

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30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes		4.2.1, 4.2.6
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes		4.2.6
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	Yes		4.2.6
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	Yes	These procedures are performed in a BSC.	4.2.6

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		Observation	Inspector Notes	USP Reference(s)
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***	Yes		5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes		4.2, 5, 20
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 5
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes		5

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes		4.2, 5
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.2.3, 5
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.1.1, 4.1.2, 5.1 Table 4
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***	Yes		5, 20

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes		5.1, 6.1, 20
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	Yes		5
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	Yes		5, 20

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH)**. ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	Yes		4.2.4, 5 Table 6

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	Yes		4.2.4, 5 Table 6
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	Yes		4.2.5, 5
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes		4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	Yes		5

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5
33.12	**PEC: (Dynamic airflow) Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	Yes	Smoke pattern testing was provided by a video.	4.2.2, 4.2.3, 5

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1
33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	Yes		5, 5.1
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	Yes		5

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5
33.17	**PEC-IVLFZ:** Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***	N/A		4.2.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3
34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A <u>unless</u> the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	N/A		5

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***	Yes		6, 6.1, 6.2
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes		6, 6.1, 6.2
35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		6, 6.1, 6.2

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes		6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes		6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes		6, 6.1, 6.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	Yes		6, 6.1, 6.2

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National Association of Boards of Pharmacy®
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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Yes		6.1, 6.3
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	Yes		6.2.2
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	Yes		6.3

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab. If no, describe observations.***	Yes		6.2.2
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to compliance statements.***	Yes		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	Yes		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes		6.1

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes		6.2.2 Box 5
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A	Air samples are sent offsite.	6.2.2 Box 5

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 6
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	Yes		6.2.3 Table 7

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to compliance statements.***	Yes		6.3
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	Yes		6.3, 6.3.1

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes	Only Category 2 preparations are compounded.	6.3, 6.3.1, 14.4.2

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41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes		6.3.2 Box 6
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days. If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.3.2 Box 7
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: >50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	Yes		6.3.3 Table 8

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		Observation	Inspector Notes	USP Reference(s)
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	Yes		6.3.3
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	Yes		3, 3.1

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	Yes		3, 3.1
42.3	Any accommodations permitted by the designated person(s) are documented.	Yes		3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes		3.1
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3

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43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		3.3
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***	Yes		3.3
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	N/A	Only disposable garb is used.	3.3

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43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***	Yes		2.3
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

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44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	No	The facility uses the Hardy Diagnostics HardyVal for CSP High-Risk Level Media-Fill Challenge Test Kits, however, there is no definition of "the most difficult and challenging procedures".	2.3, 20
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

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45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3

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45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	Yes		Box 2
	Cleaning and Disinfection			7
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? ***If no, go to compliance statements.***	Yes		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint (and sterile if used within PEC).	Yes		7.1.2
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes	Only handles are reusable and all are stainless steel or plastic.	7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes		7.1.2

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46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.*** ***Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***	Yes	Sterile TB1-3330 is the agent used.	7.1.1 Box 7 <1072>
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide.*** ***Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes	Sterile Peridox is the agent used.	7.1.1 Box 7 <1072>

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46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes		7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" sterile formulations are diluted using sterile water. ***If only ready-to-use sterile formulations are used, inspector should answer statement as N/A.***	N/A	Only RTU agents are used.	7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2 Table 10
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2, 14.4.2 Table 10
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10

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National Association of Boards of Pharmacy®
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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes		7.2 Table 10
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		4.4, 7.2 Table 10
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
	Components			9
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.1	**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	Yes		9.3.1

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	Yes		9.3.1
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	Yes		9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	Yes		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	Yes		9.3.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***	Yes		9.3.1
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	Yes		9.3.2, 9.3.3

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes." If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	Yes		9.3.2, 9.3.3
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	Yes		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	Yes		9.3.1, 9.3.2, 9.3.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	Yes		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	Yes		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	Yes		9.3.2, 9.3.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
	Equipment and Supplies			9
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***	Yes		9.1

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP<797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	Yes		9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes		9.1, 9.3.4

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	Yes		9.1
53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes		6.1, 6.2.2, 6.3.2

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes	Manual monitoring is performed.	6.2.2, 6.3.2 Box 5
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1
54.2	Makeup and/or cosmetics are removed.	Yes		3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes		3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***	N/A		3.1

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		Observation	Inspector Notes	USP Reference(s)
54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes		3.1
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2 Box 3

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2 Box 3
55.6	Soap containers are not refilled or topped off.	Yes		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2 Box 3

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
55.8	Hand dryers are not used for hand hygiene.	Yes		3.2 Box 3
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	Yes		3.3

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb and again before sterile gloves are donned, see USP <797> FAQ #97.***	Yes		3.2

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately. If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***	Yes		3.3

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing).*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	N/A	There are no gowns reused.	3.3
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Compounding of methylcobalamin 10 mg/ml aqueous injection 1 L was observed.	

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		Observation	Inspector Notes	USP Reference(s)
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		1, 2.1, 2.3
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.1.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes		8.1

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		Observation	Inspector Notes	USP Reference(s)
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	Yes		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to the compliance statements.***	Yes		15
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	Yes		15.1, 16.2

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	Yes		14.5, 15.2, 16.1
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	N/A		15.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	N/A		15.3

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates). These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes		2 Table 2, Table 3

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only." If no, go to compliance statements.***	Yes		7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes		7
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes		7.1.2

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	Yes		7.1.1, 7.1.2
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	Yes		7.1.1, 7.1.2
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning. Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7
	Sterilization and Depyrogenation			**10**
63.0	Does the pharmacy compound preparations with any nonsterile starting components? ***If the pharmacy does not compound preparations with any nonsterile starting components, inspector should answer question as N/A.***	Yes		10

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	Yes		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes		10.2 USP <1229.4>

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
65.1	Sterilization by filtration is performed in an ISO 5 environment.	Yes		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	Yes		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. ***Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."***	Yes		10.2

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	N/A		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2
65.7	Single-use filters are only used once.	Yes		4.1.2, 10.2

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes		10.3 USP <1229.1>
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	Yes		10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	Yes		10.3
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	Yes		10.3

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	Yes		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	N/A		10.3
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	Yes		10.3 USP <1229.5> USP <1229.9>

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	Yes		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	Yes	A calibrated data recorder is used.	10.3, 20

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes		10.4 USP <1229.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	Yes		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	Yes		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	Yes		10.4

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8> Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	Yes		10.4
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	Yes		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	Yes	A calibrated data recorder is used.	10.4, 20

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***	Yes		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	Yes		10.1
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	Yes		10.1 USP <1228.1> USP <85>

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Inspection Date: 3/20/2024 & 3/21/2024

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68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	Yes		10.1 USP <1228.4>
	Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**			**11**
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to the compliance statements.***	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes		11.1, 20

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 20
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	Yes		11.2 Box 10

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	Yes		11.2 Box 10
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include…Calculations."***	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	Yes		13 USP <7>

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	Yes		13
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13
71.3	Labeling on the immediate container includes an assigned internal identification number (eg; barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes		13, 14.1

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	Yes		13
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	Yes	No multiple dose compounds have been made to this date.	13
71.12	Labeling includes the route of administration, as applicable.	Yes		13

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	Yes		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	Yes		13 USP <7>
	Establishing BUDs			**14**
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 12
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, Table 13

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, Table 13

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		14.3

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National Association of Boards of Pharmacy®
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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	N/A		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	N/A		14.3 Table 14
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	N/A		14.3 Table 15
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	N/A		14.4.1 Table 14

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	N/A		14.4.3 Table 14 USP <1225>

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	N/A		14.4.4 Table 14 USP <71>
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	N/A		12.3, 14.4.4 Table 14 USP <85>
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	N/A		14.4.3 Table 14 USP <788>, <789>
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	N/A		14.4.3 Table 14 USP <1207>

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Sterile Compounding Inspection for USP <797>

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Inspector Notes	USP Reference(s)
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	N/A		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	N/A		14.5
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	N/A		14.5

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		Observation	Inspector Notes	USP Reference(s)
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	N/A		14.5 USP <51>

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		Observation	Inspector Notes	USP Reference(s)
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	N/A		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	N/A		14.5 USP <1207>
	Finished Preparation Release Checks and Tests			**12**
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1

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77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***	Yes		12.2, 14.2.3 USP <71>

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		Observation	Inspector Notes	USP Reference(s)
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	Yes		12.2, 14.2.3
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	Yes		12.2 USP <71>, <1223>

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		Observation	Inspector Notes	USP Reference(s)
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented."*** ***Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	Yes		12.3 USP <85>

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		Observation	Inspector Notes	USP Reference(s)
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	Yes		12.3
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	N/A		12.3
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	Yes		12.3 Table 13 USP <85>

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		Observation	Inspector Notes	USP Reference(s)
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	N/A		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	Yes	There have been no failed results.	12.2, 12.3
	CSP Packaging, Shipping and Transport			**19**
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes		19.2
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes		19.2

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		Observation	Inspector Notes	USP Reference(s)
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Yes		19.3
	Quality Assurance and Quality Control			**18**
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18 USP <1163>
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes		18.1, 18.2
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1

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		Observation	Inspector Notes	USP Reference(s)
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18, 20

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82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes		18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes		18.2, 20
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Yes		18.2, 18.3, 20

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		Observation	Inspector Notes	USP Reference(s)
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	Yes		18.2, 20
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes		18.1, 18.2

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83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to the compliance statements.***	Yes		18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	Yes		18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	Yes		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	Yes		18.1

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		Observation	Inspector Notes	USP Reference(s)
	Personnel Training and Evaluation - Verify records of all compounding personnel (up to 10). Use the records tab to document records reviewed.			2
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	No	There were seven employees involved in the sterile compounding and cleaning. The pharmacist/co-owner is one of the two designated persons, but he has not completed the required training and testing. As he wrote and/or approved all of the SOPs, he did not realize he had to document his training, but stated he will accomplish this training in the next 30 days.	2.2, 20 Box 1, Table 1

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85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	No	There were seven employees involved in the sterile compounding and cleaning. The pharmacist/co-owner is one of the two designated persons, but he has not completed the required training and testing. As he wrote and/or approved all of the SOPs, he did not realize he had to document his training, but stated he will accomplish this training in the next 30 days.	2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	No	There were seven employees involved in the sterile compounding and cleaning. The pharmacist/co-owner is one of the two designated persons, but he has not completed the required training and testing. As he wrote and/or approved all of the SOPs, he did not realize he had to document his training, but stated he will accomplish this training in the next 30 days.	2, 2.1, 17 Table 2, Table 3

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Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.

- Recommend also pulling supervising personnel file.

- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound (Note: frequency of competency assessment will be defined by pharmacy SOPs).

Review five (5) personnel files and document your observations. (For applicants seeking a Class E-S Non-Resident Sterile Compounding Inspection (Texas Sampling), review a total of 10 personnel records.)

- *Note: long-term employees may not have initial training available, if this is the case, you may select an alternative file. If an alternate file is not available, document length of service of long-term employee.

Inspector Note: soybean casein digest medium and trypticase soy broth are the same media.

Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.

Demonstrating Knowledge and Competency of Core Skills (Section 2.1)

USP requirements:
1. Personnel who perform or oversee compounding or *support activities* must be trained in the SOPs and trained on maintaining the quality of the environment (See Table 2).
2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions (See Table 2 and Table 3). This must be completed initially and every 12 months in at least the following areas:
-Hand hygiene
-Garbing
-Cleaning and disinfection
-Calculations, measuring, and mixing
-Aseptic technique
-Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)
-Use of equipment
-Documentation of the compounding process (eg, master formulation and compounding records)
-Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
-Proper use of PECs
-Principles of movement of materials and personnel within the compounding area
3. Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs (See Table 3).
4. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (See Table 3).
5. All training and evaluations must be documented.

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	*Initial Training and Competency in Maintaining the Quality of the Environment	*Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Practices	Notes
				Compounders and Supervising Personnel: Initially and at least every 12 months Other Personnel (examples: persons who do not compound but clean/disinfect and restock or who perform in-process checks; persons who only compound immediate use): Initially and as defined by pharmacy SOPs				
#1	Pharmacist	Compounder	Category 2 only	Yes	Yes	Yes	Yes	

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#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Missing	Missing	Missing	Missing	This is the co-owner who either wrote or approved all SOPs.
#3	Other	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#5	Other	Other	Category 2 only	Yes	Yes	Yes	Yes	This employee cleans and does not compound.
#6	Other	Other	Category 2 only	Yes	Yes	Yes	Yes	This employee cleans and does not compound.
#7	Other	Other	Category 2 only	Yes	Yes	Yes	Yes	This employee cleans and does not compound.
#8								
#9								
#10								

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Inspector Instructions
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. **2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.** **3. Select the appropriate response for each item reviewed.** **-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.** **-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.** **-Select "Missing" if the document is not present in the file.** **-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.** **4. Use the notes column to document any pertinent information.**

Hand Hygiene and Garbing Competency Evaluation (Section 2.2)
USP requirements: **1. The garbing and hand hygiene competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands.** **2. The initial competency evaluation consists of three (3) separate and complete hand hygiene observation, followed by a full garbing procedure and a GFT after garbing. The initial three (3) successful completions must be in succession—failure of any of the three (3) initial garbing competency evaluations requires repeat testing until personnel successfully complete three (3) evaluations in a row.** **3. The pharmacy uses a microbiological growth media device (eg, plates, paddles, or slides) containing general microbial growth agar (eg, trypticase soy agar [TSA]) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) that supports both bacterial and fungal growth.** **4. The media device is incubated at 30°C-35°C for no less than 48h and then at 20°C-25°C for no less than an additional five days.** **5. Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT results that exceed the defined action levels. Action level after garbing: >0 cfu/total from both hands.** **6. Documentation includes, at minimum:** **-Name of the person evaluated** **-Evaluation date and time** **-Media and components used including manufacturer, expiration date, and lot number** **-Starting temperature for each interval of incubation** **-Dates of incubation** **-Results (the number of cfu per hand must be recorded; microbial identification of the cfu is not required by the chapter for GFT)** **-Results of the evaluation and any corrective actions** **-Name of the observer and personnel reading and documenting the results**

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Hand Hygiene and Garbing Visual Observation	*Initial GFT x 3 (Post hand washing and garbing)	Subsequent GFT (Post handwashing and garbing)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially at least every 3 months Supervising Personnel: Initially and at least every 12 months				
#1	Pharmacist	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Missing	Missing	Missing	Missing	This is the co-owner who either wrote or approved all SOPs.

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#3	Other	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#5	Other	Other	Category 2 only	Yes	Yes	Yes	Yes	This employee cleans and does not compound.
#6	Other	Other	Category 2 only	Yes	Yes	Yes	Yes	This employee cleans and does not compound.
#7	Other	Other	Category 2 only	Yes	Yes	Yes	Yes	This employee cleans and does not compound.
#8								
#9								
#10								

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Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.
5. Document in notes if initial aseptic manipulation competencies are present in files (*unless long-term employee).

Aseptic Manipulation Competency (Section 2.3)

USP requirements:
1. Media-fill testing procedures simulate the most difficult compounding procedures encountered by personnel.
2. The pharmacy conducts media-fill testing as described in Box 2.
3. The final containers are incubated at 20°C-25°C and 30°C-35°C for a minimum of seven days at each temperature band.
4. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days.
5. Immediately following the media-fill test, GFT is performed on both hands and inside of an ISO Class 5 PEC. Failure is indicated by visual observation of GFT results that exceed defined action levels. Action level after media-fill testing: >3 cfu/total from both hands.
6. Immediately following the GFT, a surface sample of the direct compounding area inside the PEC is performed in accordance with USP standards for surface sample monitoring and action levels. Action level ISO Class 5: >3 cfu/media device.
7. Failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency.
8. Documentation includes, at minimum:
-Name of the person evaluated
-Evaluation date and time
-Media and components used including manufacturer, expiration date, and lot number
-Starting temperature for each interval of incubation
-Dates of incubation
-Results (for GFT, the number of cfu per hand must be recorded and for surface samples, the number of cfu per sample must be recorded. Note: microbial identification of the cfu is not required for media-fill testing)
-Results of the evaluation and any corrective actions
-Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Aseptic Manipulation Visual Observation	Media-fill	GFT (post media-fill)	Surface Sampling (post media-fill)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially and at least every 3 months Supervising Personnel: Initially and at least every 12 months					
#1	Pharmacist	Compounder	Category 2 only	Yes	Yes	Yes	Yes	Yes	
#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Missing	Missing	Missing	Missing	Missing	This is the co-owner who either wrote or approved all SOPs.

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#3	Other	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	Yes	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	Yes	
#5	Other	Other	Category 2 only	Yes	Yes	Yes	Yes	Yes	This employee cleans and does not compound.
#6	Other	Other	Category 2 only	Yes	Yes	Yes	Yes	Yes	This employee cleans and does not compound.
#7	Other	Other	Category 2 only	Yes	Yes	Yes	Yes	Yes	This employee cleans and does not compound.
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GLOSSARY USP <797>
ACD: Automated compounding device.
ACPH: Air changes per hour.
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredient, excipient, and pharmaceutical ingredient.*
Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Allergenic extract compounding area (AECA): A designated space, area, or room that is not required to be classified, with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
Allergenic extract prescription set: Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
Allergenic extract: A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.
Aseptic processing: A method by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (eg, by membrane filtration or by autoclave).

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GLOSSARY USP <797>
Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.
Batch: More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
Beyond-use date (BUD): The date, or the hour and date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
Biological safety cabinet (BSC), Class II: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
BLA: Biological license application.
Blood components: Any therapeutic constituent of blood separated by physical or mechanical means (eg, white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (eg, albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.
BMBL: Biosafety in Microbiological and Biomedical Laboratories.
Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
Bulk drug substance: See the entry for *Active pharmaceutical ingredient.*
Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.

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GLOSSARY USP <797>
Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits in *Table 13* for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
CDC: Centers for Disease Control and Prevention.
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
CFU: Colony-forming units.
Classified area: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for *ISO class).*
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Cleaning: The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleanroom suite: A classified area that consists of both an anteroom and buffer room.
Component: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
Compounded stock solution: A sterile mixture of components that is used to compound additional CSPs.
Compounding area: The area where compounding is occurring (ie, a cleanroom suite, inside the perimeter of the SCA, or AECA).
Compounding aseptic containment isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
Compounding aseptic isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.

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GLOSSARY USP <797>
Compounding record (CR): Documents the compounding of each CSP.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.
Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE): A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Critical site: A location that includes any component or fluid pathway surfaces (eg, vial septa, injection ports, and beakers) or openings (eg, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (eg, ambient room or HEPA filtered), moisture (eg, oral and mucosal secretions), or touch contamination.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs.
Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for *Dynamic operating conditions).* This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see the entry for *Visual smoke study).*
Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

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GLOSSARY USP <797>
ECV: Endotoxin challenge vial.
EPA: US Environmental Protection Agency.
Excipient: See the entry for *Added substance.*
FDA: US Food and Drug Administration.
Filter integrity test: A test (eg, bubble point test) of the integrity of a sterilizing-grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.
Final yield: The total number of containers prepared at the end of the compounding process prior to release testing.
First air: The air exiting the HEPA filter in a unidirectional air stream.
Formulation: The specific qualitative and quantitative composition of the final CSP.
Garb: Items such as gloves, garments (eg, gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of contamination of CSP(s).
GFT: Gloved fingertip and thumb testing.
Hazardous drug (HD): Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
High-efficiency particulate air (HEPA) filtration: Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
HVAC: Heating, ventilation, and air conditioning.
Integrated vertical laminar flow zone (IVLFZ): A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
IPA: Isopropyl alcohol.

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GLOSSARY USP <797>
ISO class: An air-quality classification from the International Organization for Standardization.
ISO: International Organization for Standardization.
Label: The part of the labeling on the immediate container.
Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container.
Laminar airflow system (LAFS): A device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.
Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
Line of demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom.
Low-lint wiper: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from or easily removed from the wiper material in a dry condition.
Master formulation record (MFR): A detailed record of procedures that describes how the CSP is to be prepared.
MEA: Malt extract agar.
Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
Monograph: A quality documentary standard within *USP–NF* that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Multiple-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed to contain more than one dose of the sterile product. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See <659> Injection Packaging Systems, Multiple-dose container.

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GLOSSARY USP <797>
One-step disinfectant cleaner: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
Oversight: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed, even if not physically present.
Pass-through chamber: An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter: A visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA.
Pharmaceutical isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. [Note—A CAI or CACI is not a pharmaceutical isolator.]
Pharmacy bulk package: A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See <659> *Injection Packaging Systems, Pharmacy bulk package.*
Positive-pressure room: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.
PPE: Personal protective equipment.
Preservative: A substance added to inhibit microbial growth.
Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
Probability of a nonsterile unit (PNSU): The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [Note—This is also called the sterility assurance level (SAL).]
Pyrogen: A substance that induces a febrile reaction in a patient.
Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

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GLOSSARY USP <797>
Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
Reconstitution: The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.
Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.
Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.
SDA: Sabouraud dextrose agar.
Secondary engineering control (SEC): The area where the PEC is placed (eg, a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.
Single-dose containers: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659> Injection Packaging Systems, Single-dose container.
SOP: Standard operating procedure.
Specification: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
Sporicidal disinfectant: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

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GLOSSARY USP <797>
Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Sterility assurance level (SAL): See the entry for *Probability of a nonsterile unit* (PNSU).
Sterility: The absence of viable microorganisms.
Sterilization by filtration: Passage of a gas or liquid through a sterilizing-grade membrane to yield filtrates that are sterile.
Sterilizing-grade filter: Filter membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeters of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22- or 0.2-µm pore size.
Terminal sterilization: The application of a lethal process (eg, steam, dry heat, irradiation) to sealed containers for the purpose of achieving a predetermined PNSU of greater than 10−6 or a probability of less than one in one million of a nonsterile unit.
TSA: Trypticase soy agar.
Unclassified space: A space not required to meet any air cleanliness classification based on the ISO.
Unidirectional airflow: Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.
Verify: To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Visual smoke study: A test, used in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow, in which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see the entry for *Dynamic airflow smoke pattern test*).
Workflow management system: Technology comprised of hardware and/or software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

	General Information and Scope:	Observatio	Notes
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that **require** all the containment requirements of USP <800>?	Yes	
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	Yes	Hazardous APIs handled include anastrozole, apomorphine, finasteride, fluorouracil, estrogen, estradiol, DHEA, progesterone, spironolactone, testosterone, and tretinoin.
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gasses)? *If yes, please list.*	N/A	
2.00	Does the pharmacy handle any drugs on the NIOSH list that **do not** require all containment requirements of <800>?	No	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	N/A	
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	N/A	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	N/A	
	List of Hazardous Drugs		
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	Yes	Hazardous APIs handled include anastrozole, apomorphine, finasteride, fluorouracil, estrogen, estradiol, DHEA, progesterone, spironolactone, testosterone, and tretinoin.
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	Yes	The review has not been documented to this date but is planned for November 2024,12 months after its original compilation.
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Yes	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Yes	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Yes	
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	Yes	
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	No	
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);	Yes	
8.02	Dosage form;	No	
8.03	Risk of exposure;	Yes	
8.04	Packaging;	Yes	
8.05	Manipulation; and	Yes	

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e-Profile ID: 1259083

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		Observatio	Notes
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	Yes	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*	Yes	The original review was completed in March 2024 and will be reviewed again in March 2025, 12 months after its original compilation.
	Personnel Responsibilities		
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Yes	
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	Yes	
	Documentation and Standard Operating Procedures (SOPs)		
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		
10.01	**Receiving:** Contacting HD residues on packaging, work surfaces, floors	Yes	

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
10.02	**Dispensing**: Counting or packaging tablets and capsules	N/A	
10.03	**Compounding/other manipulations:** Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Yes	
10.04	**Administration and other patient care activities** (if applicable).	N/A	
10.05	**Spills**: Spill generation, management, and disposal.	Yes	
10.06	**Transport**	Yes	
10.07	**Waste**: Collection and disposal of HD waste and trace contaminated waste	Yes	
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Yes	The review has not been documented to this date but is in process for this month (March), 12 months after the development of most SOPs.
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc). *Describe whether P&Ps are available electronically, by paper, or both.*	Yes	SOPs are electronic and hard copy.

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e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
13.00	SOPs address at a minimum: *If no, document "missing" in Inspector Notes for each SOP topic*		**Please note NABP did not review each SOP for alignment on USP <800>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**
13.01	Hazard communication program plan	Yes	
13.02	Competent personnel	Yes	
13.03	Occupational safety program	Yes	
13.04	Designation of HD areas	Yes	
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Yes	
13.06	A list of HDs	Yes	
13.07	Storage of HDs	Yes	
13.08	Compounding of HDs	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
13.09	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C PECs], containment secondary engineering control [C SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Yes	
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Yes	
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:		
13.11.01	Agents used	Yes	
13.11.02	Dilutions, if used	N/A	Only RTU agents are used.
13.11.03	Frequency	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)	Yes	
13.11.05	Documentation requirements	Yes	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Yes	
13.13	If a shipping container appears damaged and **does not need to be opened:**		
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Yes	
13.13.02	Labeled as "hazardous"; and	Yes	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Yes	
13.14	If a damaged shipping container **must be opened:**		
13.14.01	Container is sealed in plastic or an impervious container;	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	Yes	
13.14.03	container is placed on a plastic-backed preparation mat;	No	
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	Yes	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	Yes	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Yes	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	Yes	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	N/A	
13.15	Safe work Practices SOPs	Yes	
13.16	Dispensing SOPs	Yes	
13.17	Packaging and labeling SOPs	Yes	
13.18	Transport SOPs	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
13.19	Administering SOPs, if applicable	N/A	
13.20	***Recommendation: Environmental monitoring (eg, wipe sampling) SOPs***	Yes	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	Yes	
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		
13.22.01	Size and scope of spill;	Yes	
13.22.02	Responsible person for handling spills;	Yes	
13.22.03	Location of spill kits and clean-up materials;	Yes	
13.22.04	Capacity of the spill kits;	Yes	
13.22.05	PPE to be worn during spills;	Yes	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	Yes	

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		Observatio	Notes
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	Yes	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	Yes	
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	No	This is not current, however, the Quality Director stated the program is in the development process.
14.00	The **hazard communication program** SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Yes	
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		
15.01	A written plan that describes how the standard will be implemented;	Yes	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Yes	

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		Observation	Notes
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	Yes	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	Yes	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Yes	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Yes	
	Personnel Training —*Check four employee files for documentation*		
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Yes	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	Yes	
18.00	For non sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	Yes	

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		Observation	Notes
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	Yes	
20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.	Yes	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Yes	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Yes	
23.00	HD training, based on employee file review, all of the following are present:		
23.01	Overview of pharmacy's HD list and their risks;	Yes	
23.02	Review of the SOPs related to HDs;	Yes	
23.03	Proper use of PPE;	Yes	
23.04	Proper use of equipment and devices (eg, engineering controls);	Yes	

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	Yes	
23.06	Response to known or suspected HD exposure;	Yes	
23.07	Spill management;	Yes	
23.08	Proper disposal of HDs and trace-contaminated materials; and	Yes	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	Yes	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	Yes	
	Personal Protective Equipment		
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	Yes	
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:		
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
26.02	Storage;	Yes	
26.03	Transport;	Yes	
26.04	Nonsterile Compounding (if performed by the pharmacy);	Yes	
26.05	Sterile Compounding (if performed by the pharmacy);	Yes	
26.06	Administration, if applicable;	Yes	
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Yes	
26.08	Spill control;	Yes	
26.09	Waste disposal; and	Yes	
26.10	If administering injectable antineoplastics, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	N/A	
27.00	Disposable PPE is not reused.	Yes	
28.00	Reusable PPE is decontaminated and cleaned after each use.	N/A	

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		Observatio	Notes
29.00	**Gloves**: The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 -- or its successor -- and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Yes	
29.01	**Recommendation**: Are *chemotherapy gloves worn for handling all HDs including non antineoplastics and for reproductive risk only HDs?*	Yes	
29.02	Chemotherapy gloves are powder free.	Yes	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Yes	
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	Yes	
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Yes	
29.06	**Recommendation**: Are *chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?*	Yes	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
30.00	**Gowns:** The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding,based on standards or assessment of risk).	Yes	
30.01	Gowns are disposable.	Yes	
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Yes	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Yes	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Yes	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Yes	
30.06	Gowns worn in HD areas are not worn to other areas.	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
31.00	**Head, hair** (beard and moustache, if appropriate), **and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Yes	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C SEC and doffed when exiting the C SEC.	Yes	
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	Yes	
32.00	**Eye and Face Protection**: The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C PEC), if required.	Yes	
32.01	If a risk to eyes, goggles (or a full face respirator) are worn. *Eyeglasses or safety glasses with side shields are not substituted for goggles.*	Yes	
32.02	If a risk to face and eyes, goggles plus a face shield (or a full face respirator) are worn.	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
33.00	**Respiratory Protection:** The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit tested, when required).*	Yes	N-95 masks and fit-tested chemical cartridge respirators are available.
33.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
33.03	Full-face piece, chemical cartridge-type respirator;	No	
33.04	PAPR; and/or	No	
33.05	Other (describe in notes).	N/A	
34.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	
35.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
35.03	Full-facepiece, chemical cartridge-type respirator;	No	
35.04	PAPR; and/or	No	
35.05	Other (describe in notes).	N/A	
36.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	
37.00	**Disposal of Used PPE: Is** all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Yes	

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		Observatio	Notes
37.01	Worn PPE is placed in an appropriate HD waste container.	Yes	
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	Yes	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C PEC or contained in a sealable bag for discarding outside the C PEC.	Yes	
	Facilities and Engineering Controls		
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	Yes	
38.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	Yes	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	Yes	
39.00	There are designated HD areas for any of the following:		
39.01	Receiving and unpacking of HDs	Yes	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observation	Notes
39.02	Storage of HDs	Yes	
39.03	Nonsterile HD compounding (if performed by the pharmacy)	Yes	
39.04	Sterile HD compounding (if performed by the pharmacy)	Yes	
40.00	***Recommendation**: If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?*	Yes	There is an onsite generator.
41.00	**Receipt**: Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	Yes	All HDs are received at the standard receiving area and immediately moved to the negative pressure NS area.
41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. *Indicate the type of environment. If the environment is positive pressure, it is non-compliant.*	Yes	All HDs are received at the standard receiving area and immediately moved to the negative pressure NS area.
41.01.01	Neutral	Yes	The air pressure is neutral in the receiving area.
41.01.02	Negative	Yes	The air pressure is negative in the unpacking area.

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		Observation	Notes
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C SEC).	Yes	
43.00	**Storage:** Are HDs stored in a manner to minimize accidental exposure? *Describe.*	Yes	
43.01	HDs are not stored on the floor.	Yes	
43.02	HDs are stored in a manner to minimize breakage and spillage.	Yes	HDs are stored and transported in a separate plastic bin.
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, raised front lips on shelving in earthquake prone areas).	N/A	
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non HDs.	Yes	
44.01	These HDs are stored in an externally ventilated, negative pressure room.	Yes	
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	Yes	

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		Observatio	Notes
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C SCA]).	Yes	
44.04	**Recommendation**: *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	N/A	
45.00	If non antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with other non HD inventory, there is a written policy/SOP addressing it.	N/A	
46.00	**Compounding**: There are appropriate engineering controls to protect the HD preparation from cross contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	Yes	
47.00	All HD compounding are performed within a C PEC located in a C-SEC room.	Yes	
47.01	The C SEC for both sterile and nonsterile HD compounding has all of the following:		
47.01.01	Has fixed walls;	Yes	
47.01.02	Is externally vented;	Yes	

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47.01.03	Is able to meet (12) or exceed ACPH requirements;	Yes	
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Yes	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Yes	
48.00	The C PEC operates continuously if it supplies some or all of the negative pressure in the C SEC or if it is used for sterile compounding.	Yes	
49.00	There is a sink readily available for handwashing on the hazardous side.	Yes	
49.01	There is an eyewash station readily available.	Yes	
49.02	Water sources and drains are a minimum of 1 meter away from the C PEC.	Yes	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01 54. If no, skip to 55:	Yes	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):		
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	Yes	
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	No	

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50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding:**		
50.02.01	Class I biological safety cabinet (BSC)	No	
50.02.02	Class II BSC	Yes	
50.02.03	Containment ventilated enclosure (CVE)	No	
50.02.04	Compounding aseptic containment isolator (CACI)	No	
50.02.05	Other, describe	N/A	
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):		
51.01	Is externally vented *(preferred)* ; **and/or**	Yes	
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	Yes	
52.00	Does the pharmacy use the same C PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	No	
52.01	Is **nonsterile HD compounding** only "occasional"? */ If yes, please describe frequency and quantity.*	N/A	
52.02	Is the **nonsterile HD compounding** activity only occurring when sterile HD compounding is not being performed?	N/A	

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52.03	Is the C PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	N/A	
53.00	The C SEC has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non shedding. *If non-compliant describe.*	Yes	
55.00	Does the pharmacy engage in **sterile HD compounding**? If yes, complete 55.01 61.02.03. If no, skip to 62.	Yes	
55.01	Select the type(s) of containment primary engineering control(s) used for **sterile HD compounding:**		
55.01.01	CACI	No	
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)	No	
55.01.03	Class II BSC, Type A2 (formerly Type B3)	No	
55.01.04	Class II BSC, Type B1	No	
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	Yes	
55.01.06	Class III BSC	No	

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Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
55.01.07	LAFW (not for antineoplastics)	No	
55.01.08	CAI (not for antineoplastics)	No	
56.00	The C PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	Yes	
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	Yes	
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non HD preparations, is the non HD preparation placed into a protective outer wrapper during removal from the C PEC?	N/A	
58.01	If used for both, is the non HD preparation labeled to require PPE handling precautions?	N/A	
59.00	If the C SEC is an unclassified containment segregated HD compounding area (C SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	N/A	
59.01	The C SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
59.02	A handwashing sink is at least one meter or more away from the C-PEC	Yes	
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA		The sink is in the anteroom outside of the SEC.
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	N/A	
60.01	The buffer room has fixed walls.	N/A	
60.02	The buffer room is externally vented.	N/A	
60.03	The buffer room has HEPA filtered supply air.	N/A	
60.04	The buffer room has at least 30 ACPH.	N/A	
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	N/A	
60.06	The anteroom has fixed walls.	N/A	
60.07	The ante room has a minimum of 30 ACPH of HEPA filtered supply air.	N/A	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	N/A	

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	N/A	
61.00	If the negative pressure HD buffer room is entered through a positive pressure non HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	N/A	
61.01	There is a design and method to contain and minimize HD contamination when **transporting** HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	N/A	
61.02	Indicate how HD contamination is minimized:		
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room).*	Yes	
61.02.02	Use of sealed containers	Yes	
61.02.03	Other, *describe*	Yes	Training is also a part of the minimization of the contamination process. Disposable PPE and equipment are used when possible.

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
Environmental Quality and Control - Surface wipe sampling			
62.00	**Recommendation: Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:	Yes	
62.01	Interior of C-PEC and equipment within the C-PEC	Yes	
62.02	Pass-through chambers	Yes	
62.03	Surfaces in staging or work areas near the C-PEC	Yes	
62.04	Areas adjacent to the C-PEC (eg,. floors directly under, staging, and dispensing areas)	Yes	
62.05	Areas immediately outside the HD buffer room or the C-SCA	No	
Receiving			
63.00	**Recommendation:** HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.	Yes	
64.00	HDs are delivered to the HD storage area immediately after unpacking.	Yes	
65.00	A spill kit is readily accessible in the receiving area.	Yes	

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Hazardous Drugs -Handling in Health Care Settings

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Yes	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Yes	
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C PEC.\	Yes	
68.00	Damaged packages are considered spills and reported to the designated person. ***List last date of damaged package receipt.***	Yes	There have been none.

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
Labeling, Packaging, Transport, and Disposal			
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Yes	
70.00	Labeling processes do not introduce contamination into non HD handling areas.	Yes	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Yes	
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	Yes	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		
73.01	Labeling specified in SDS for transport;	Yes	
73.02	Storage and disposal instructions; and	Yes	
73.03	Labeled with HD category.	No	The facility believes they comply with the carrier's requirements, but there is no category on the labeling of HDs shipped

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
Dispensing, Packaging, and Compounding Processes			
74.00	Counting of antineoplastics is done by hand (eg, not placed into automated counting devices).	Yes	
75.00	Clean, dedicated (not used for non HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Yes	Disposable equipment is used to the fullest extent possible. Other equipment is dedicated.
75.01	**Recommendation:** Equipment is decontaminated after every use.	Yes	
75.02	**Recommendation:** When compounding, a plastic backed preparation mat is placed on the C PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	No	
75.02.01	Immediately if a spill occurs	No	
75.02.02	Regularly during use	No	
75.02.03	At the end of a shift	No	
76.00	APIs or other powdered HDs are handled in a C PEC during particle generating activities, such as crushing, opening capsules, and weighing powders.	Yes	

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)			
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	Yes	
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Yes	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant:*	Yes	
79.01	Between compounding of different HDs	Yes	
79.02	At least daily when used	Yes	
79.03	Any time a spill occurs	Yes	
79.04	Before and after certification	Yes	
79.05	Any time voluntary interruption occurs	Yes	
79.06	If the ventilation tool is moved	Yes	
80.00	HD containers are wiped down prior to placing them in the C PEC and the solution used does not alter the product label.	Yes	

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Facility Name: SNF Holdings LLC dba VIOS Compounding Pharmacy

e-Profile ID: 1259083

Inspection Date: 3/20/2024 & 3/21/2024

		Observatio	Notes
81.00	Areas, other than the work surface of the C PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Yes	
82.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	Yes	
	Spill Control		
83.00	Spills are contained and cleaned immediately.	Yes	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Yes	
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	Yes	
86.00	There are signs available to restrict access to spill areas.	No	The area is evacuated and no personnel are allowed in the area.
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Yes	
88.00	Spill materials are disposed of as hazardous waste.	Yes	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	Yes	There have been no spills in the last year.

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☒ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 02575	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: veterinary compounding	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FW1055880 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: veterinary

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Toll-free line available 24/7.

Section 1: General Information

Pharmacy Name: Wedgewood Pharmacy LLC

Physical Address: 4340 Georgetown Road

City: Lexington State: KY Zip: 40511

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 859-389-7470 Toll Free # (NAC 639.708, NRS 639.23286): 888-934-5678

Fax: 859-381-9252 Contact Email: brvlicensing@bluerabbit.vet

Website: www.wickliffe.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Nicholas Kirkpatrick

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): ~~19518~~ 22165

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Nicholas Kirkpatrick	NV Pharmacist Registration #: ~~19518~~ 22165
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Wedgewood Holdings Inc

Corporation/Organization Name: Wedgewood Pharmacy LLC

Mailing Address: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 800-331-8272 Email: licensing@wedgewoodpharmacy.com

Contact Person Name: Joe Costa

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President/COO (title) for Wedgewood Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Joseph Costa

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/15/2024

Date

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Wedgewood Pharmacy LLC

NV Pharmacy or Outsourcing facility license # (if applicable): PH02575

Physical Address: 4340 Georgetown Road

City: Lexington State: KY Zip: 40511

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 859-389-7470 Toll Free # (NAC 639.708, NRS 639.23286): 859-389-7470

Fax: 859-381-9252 Contact Email: licensing@wedgewoodpharmacy.com

Website: www.wedgewoodpharmacy.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Nicholas Kirkpatrick

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22165

Name of Person with direct knowledge of compounding procedures: Nicholas Kirkpatrick

Email of Person with direct knowledge of compounding procedures: nick.kirkpatrick@wickliffeRx.com

Telephone of Person with direct knowledge of compounding procedures: 859-389-7470

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Altrenogest 225mg/mL Injectable
Ammonium sulfate 0.75% Injectable
Caco Copper Injectable
Estrone 5mg/ml Injectable
Glucosamine 200mg/mL Injectable
Histrelin (as Acetate) 0.5mg/mL Injectable
Iodine in Oil 2% Injectable
Progesterone 200mg/mL Injectable
Reserpine 2.5mg/mL Injectable
Romifidine 1% Injectable
Stanozolol 50mg/mL Injectable
Tryptophan 100mg/mL Injectable

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
BUDs are extended based on stability indicating tests that include sterility and container closure tests for sterile compounded products.

6. What laboratory performs this additional testing?
Name: ARL Bio Pharma and CIAL
Address: 840 Research Pkwy #546 (ARL); 4760 Castleton Way, Suite A (CIAL)
City: Oklahoma City (ARL); Castle Rock, CO 80109 (CIAL) State: OK (ARL) Zip: 73104 (ARL)
Telephone: 405-271-1144 (ARL); 800-788-9922 (CIAL)

7. What is your procedure for visual inspection of compounded sterile products?
See following SOP enclosed
- Visual/Physical Inspection of CSPs.

8. How often do you perform glove fingertip and medial fill testing?
Initially and quarterly for compounders, initially and annual for supervisors

9. What is your policy if an employee fails a glove fingertip or media-fill test?
A failed GFT would be sent for speciation. Media fill test is sent to ARL and speciation would be performed at time of growth. Re-training, observation & re-testing would take place.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initial and quarterly training are completed by aseptic compounders, which includes gloved fingertip, media fill, hand hygiene and garbing, hood cleaning, aseptic technique, and cleaning and disinfecting procedures.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
See the following SOPs enclosed:
1. Primary Enginerring Control (Isolator) Cleaning
2. Cleaning and Sanitizing Procedures for Sterile Areas
3. Clean Room Material Washing
4. Autoclave Procedures
5. Depyrogenation and Dry Heat Sterilization Procedures
6. Hand Hygiene Procedure
7. Aseptic Compounding Environment

12. Who performs the sterile compounding process at your facility?
Aseptic compounding technicians and pharmacists

13. Who is responsible and accountable for the sterile compounding process at your facility?
Tarek Khalid (Sterile Compounding Supervisor)

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
See following enclosed SOPs:
1. Shipped/Delivered Compounded Preparations
2. Packing & Shipping

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?
CACI

2. Is your BSC or CACI vented 100% to the outside?	☒ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☒ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☒ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☒ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☒ No

7. If yes, list the name of the device:
n/a

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?
Patient package insert provided with each hazardous dispensing from Plumb's online database. Handling of hazardous ddrugs included on drug and prescription label.

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
All new and existing personnel are continually trained by our hazardous drug designated person to promote patient safety, worker safety, and environmental protection as described in USP 800

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

Altrenogest 225mg/mL Injectable
Ammonium sulfate 0.75% Injectable
Caco Copper Injectable
Estrone 5mg/ml Injectable
Glucosamine 200mg/mL Injectable
Histrelin (as Acetate) 0.5mg/mL Injectable
Iodine in Oil 2% Injectable
Progesterone 200mg/mL Injectable
Reserpine 2.5mg/mL Injectable
Romifidine 1% Injectable
Stanozolol 50mg/mL Injectable
Tryptophan 100mg/mL Injectable

2. What sterilization methods are utilized at your facility?

Steam and filter sterilization

3. Does your facility utilize biological indicators? ■ Yes ☐ No

4. If yes, describe how they are utilized:

BI's are included with each run of autoclave as one means to verify steam sterilization cycles. BI's are included with each oven cycle as one means to verify depyrogenation cycles.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nicholas Kirkpatrick

Name of Person who Completed the Form

Pharmacist in Charge/General Manager

Title

Signature (copies or stamps not accepted)

4/8/24

Date

Board Use Only	Date Received: 4/17/24 Date Approved: _____ Approved By: _____

Visual/Physical Inspection of CSPs

	Name	*Signature*	*Date*
Pharmacist-In-Charge			
Employee Signature of Acceptance:			

POLICY: *All injectable preparations (CSPs) shall be visually and physically inspected at a rate of 100% prior to dispensing. Visual and physical inspection shall consist primarily of post-compounding inspection. Pre-release and pre-dispensing visual and physical inspection shall be supplemental to post-compounding inspection to ensure quality of CSPs.*

PURPOSE: *Visual and physical inspection of vials after compounding allows for detection of porticulates, insufficient container closures, unexpected CSP characteristics, and other apparent defects.*

RESPONSIBILITY: *Pharmacist-in-Charge, Aseptic Pharmacists, and Staff Pharmacists*

PROCEDURE:

Post compounding visual inspection should be done promptly after compounding has been completed and prior to labeling. Post-compounding inspection consists of: particulate inspection, container closure inspection, and other apparent defects inspection. Pharmacists performing post compounding visual inspection must be adequately trained in visual inspection, particularly pertaining to the detection of visible foreign particulote matter.

- *Particulate inspection-CSPs should be essentially free from visible foreign porticulate matter. The presence of particulates should be assessed by placing the vial under a bright, high-intensity light against a black and a white background for a minimum of 5 seconds per background. Minimal agitation should be used to suspend and visualize any particulates through a combination of gentle inversion and gentle swirling. Care must be taken to avoid the production of air bubbles as this significantly hinders detection of particulates. Viols thot contain visible foreign particulate matter shall be rejected. Particulate inspection should be done in a manner that ollows for sufficient breaks to prevent eye-strain and facilitate porticulate detection.*
    - *Key Aspects of particulate inspection:*
        - *100% inspection*
        - *High intensity light*
        - *Black and white background; 5 seconds minimum per background*
        - *Gentle inversion/swirling; minimal air bubbles*
        - *Rejection of all vials containing visible particulates*
    - *Particulate inspection shall be modified and combined with particle size inspection for suspensions. Particulate inspection of suspensions should be done under a bright light against a dark background.*
- *Container Closure inspection- Container closure system shall be inspected and determined to be robust enough to prevent microbiol penetration.*

- *Other apparent defects inspection- Vials should be inspected for any other defects (i.e. glass imperfections) that might affect the quality of CSPs.*
- *CSP Characteristics- Solutions shall retain the characteristics described in the log (color, clarity, etc.). Suspensions shall retain the characteristics described in the log and additionally have a uniform, small particle size. Articles which have not retained proper CSP characteristics shall be discarded. Rejection of the entire batch may be warranted at the discretion of the inspecting pharmacist if a significant number of articles do not retain the expected CSP characteristics.*
- *Quality Limit- Based on 100% inspection and current process capabilities, the acceptable quality limit for rejects is set at 10% of the actual batch yield. Any lot that does not meet the acceptable quality limit shall be investigated thoroughly.*
    - *Reject reason will be clearly defined and documented in the compounded batch record*
    - *Reject reasons may include:*
        - *Overfilled vial*
        - *Underfilled vial*
        - *Particulate observed on white background*
        - *Particulate observed on black background*
        - *Other with an explanation of the specific reject reasan*
    - *Reject reasons will be trended quarterly to identify trends associated with API, vial size or method of sterilization.*
- *Pre-release visual inspection shall be done immediately prior to release of CSPs from quarantine and is a brief inspection compared to post-compounding inspection. The primary objective of pre-release visual inspection is to ensure that no changes have occurred during storage in the quarantine area.*
    - *CSP appearance inspection- CSPs shall be inspected and appearance determined to be consistent with desired properties (i.e. clarity of solutions, ease of dispersion for suspensions).*
    - *Container closure inspection- Container closure shall be briefly inspected to ensure that the clasure system still prevents microbial penetration.*
- *Pre-dispensing visual inspection shall be done immediately prior to dispensing of CSPs ond is a brief inspection during final verification. The primary objective of pre-dispensing visual inspection is to ensure that no changes have occurred during storage prior to dispensing.*
    - *CSP appearance inspection- CSPs shall be inspected and appearance determined to be consistent with desired properties (i.e. clarity of solutions, ease of dispersion for suspensions).*
    - *Container closure inspection- Container closure shall be briefly inspected to ensure that the closure system still prevents microbial penetration.*

Primary Engineering Control (Isolator): Certification/Testing, Operation, and Maintenance

Primary Engineering Control (Isolator): Certification/Testing, Operation, and Maintenance

	Name	*Signature*	*Date*
Pharmacist-In-Charge			
Employee Signature of Acceptance:			

Purpose

To define a procedure for certification/testing, operation, and maintenance of primary engineering controls (isolotors). Properly certified, tested, and operated isolators are critical in achieving and maintaining the sterility of CSPs.

Responsibility

It is the responsibility of the PIC and the supervising pharmacists to ensure the procedure is followed. All clean room personnel are responsible for following this procedure.

Procedure

Primary Engineering Controls

Primary engineering controls shall be designed to maintain ISO 5 or better conditions. All aseptic manipulations shall take place in the PEC under ISO 5 or better conditions. Aseptic technique and manipulations are detailed in the aseptic technique and manipulations procedure.

Per USP <797>, ISO 5 conditions are:

- *Not more than 3,520 0.5um or larger particles per m3 under dynamic operating conditions*

Primary engineering controls may include: CAIs, CACIs, LAFWs, etc.

Certification/Testing

Certification of primory engineering controls may be done in-house or by an outside certification company.

Equipment used for certification and testing sholl conform to the manufacturer's standards for maintenonce and calibration.

CETA or similar guidelines that outline specific stondards shall be used to perform certificotion and testing of primary engineering controls. These standards shall include, at a minimum:

- *Non- viable porticle counts not more than 3,520 0.5um or larger particles per m3 under dynamic operating conditions*
- *Air flow/velocity*
- *HEPA Filter Leak Testing*
- *Direct compounding area smoke testing demonstrating unidirectionol air flow under dynamic operating conditions*

Certifications and testing sholl be done at a minimum of seml-annuolly, unless otherwise required.

Viable air sampling and surface sampling are required as part of ongoing testing of primary engineering controls and are described in their respective procedures.

Re-certification and re-testing of primary engineering controls shall be done whenever relocated as part of clean room construction or re-organization, or when repairs deemed likely to affect isolator performance are required. Short, careful, deliberate movements of the primary engineering controls to allow for cleaning behind do not require re-certification and re-testing.

Operation

The operation of primary engineering controls requires proper knowledge of their function and use. Properly functioning and maintained but poorly operated primary engineering controls may not maintain ISO 5 conditions. As such, it is critical for them to be properly operated.

Cleaning of primary engineering controls is vital to their aperatian and is described in the PEC cleaning procedure.

Proper use of primary engineering controls while performing aseptic manipulations is described in the aseptic technique and manipulations procedure.

Where equipped, primary engineering control pressures shall be recorded daily and trended.

Recovery times allow for re-establishment of appropriate ISO conditions whenever portions of the isalatar are opened for material tronsfer or cleaning. Minimum recovery times for the primary engineering controls ore as follows:

- *Pass-Through In/Out Transfer: 60 seconds prior to opening af main chamber*
- *Front Panel Opening: 30 minutes priar to compounding*

All materials transferred into the isolator during use/operation shall be cleaned as per the material transfer procedure.

Primary engineering controls are designed for continuaus aperation. In the event that a primary engineering control is not operated continuously, a sporicidal disinfection deep clean must be performed followed by period of at least 30 minutes after closing the front panel prior to compounding. Additional corrective or preventive action may be required depending an the nature af the interruption in operation.

Maintenance

Maintenance may be required as part of certificotian or on an ongoing basis. Proper maintenance shall be done to ensure adequate performance of the primary engineering control. The following maintenance is required by the operator's manual:

- *HEPA Filters- As required by certifier*
- *Pre-Filters- Annually, ot minimum (inspect monthly)*
- *Gountlet gloves- Daily (when in use)*
- *Sleeves- Semi-Annually, at minimum (inspect daily)*
- *Sleeve accessories (o- rings, cuff, etc.)- As needed*

Version # 005.001

Cleaning and Sanitizing Procedures for Sterile Areas

	Name	*Signature*	*Date*
Pharmacist-In-Charge			
Emplayee Signature of Acceptance:			

PURPOSE: *To develop and maintain an organized and clean environment for the preparation of Sterile preparations.*

RESPONSIBLE: *The PIC, the head Aseptic Pharmacist and the Aseptic Technicians are responsible for ensuring compliance with this protocol.*
Chorts and logs are maintained as a means of compliance. The PIC shall verify that all cleaning is being sufficiently completed according to protocol and that staff performing the cleaning have been adequately troined.

INFORMATION: *All individuals entering the room are expected to wear head and shoe covers, as well as appropriate garb, as minimum attire. See Gowning and Garbing P&P for details.*

In general, cleaning should be done from the cleanest area to the dirtiest area. To minimize cross-contamination, cleaning should also be done from top to bottom. For example, in a monthly cleaning, the order would be: ceilings; walls ond windows; exteriors of process equipment and cabinets; countertops ond other horizontal surfaces; and at last, floors.

This is the responsibility of trained pharmacy staff (pharmacists and technicians), and should be performed at the beginning of each shift. Spills and residue in the hood and adjacent surfaces should be disinfected with 70% isopropyl alcohol as necessary. The isopropyl alcohol should be allowed to dry before compounding is begun. All cleaning tools should be for single-use only, non-shedding, and for use only in controlled area.

During Shifts: Surfaces in the isolator within arm's reach can be cleaned using wipers and solutions - 70% isopropyl alcohol (IPA). Wipers should be "low-linting" — that is, wipers should not leave particles and fibers behind when they are used to clean surfaces. A non-woven polyester/cellulose wiper can be used. Wipers that ore pre-wetted with 70% IPA shall be used. They can be also be wetted at the time of use with the solution of choice. Be sure wipers are not dripping with solution — an overly wet wiper can redisperse contaminonts and can increase the chances of the solution itself becoming a contamination source. ***The isopropyl alcohol should be allowed to dry before compounding is begun.*** *Wipers should be folded so that the entire surface of the wiper can be used. Typically wipers are quarter folded, and then refolded after every wipe of the surface, to contain and remove the contamination. In this manner, there are eight different surfaces of the wiper exposed and able to be used for wiping. Wiping should be done in overlapping linear strokes from clean to dirty or dry to wet. After all eight surfaces have been used, the wiper (and its captured contamination) should be discarded in an appropriate container. The appropriate cleaning tool may be used to clean the isolator.*

The ante, buffer and clean room(s), will be cleaned and disinfected according to guidelines below: *In addition to the sterile compaunding areas, counters and work surfaces shall be cleaned and disinfected daily. Floors in all areas, including the buffer area, anteroom, and compaunding area, are to be cleaned and disinfected daily. All mopping should take place when no compounding is in progress.*

Walls and ceilings shall be cleaned monthly when no compounding is in process.

All other surfaces, carts, and storage area shelving, shall be cleaned and disinfected at least monthly, again when no compounding is in progress. Storage shelving in the buffer or clean area should be emptied of all supplies, and then cleaned.

Floors in the buffer area, as well as the anteroom area, should be mopped daily with a multi-purpose antifungal, ontivirucidol and antibacterial agent, when no aseptic operations are in progress. Mopping should be performed using approved agents described in written procedures. Only approved cleaning and sanitizing agents are used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues. Their schedules of use and methods of application are in accord with written procedures. All cleaning tools, such as wipers, sponges, and mops are non-shedding and dedicated to use in the buffer or clean area. Floors are cleaned using flat mops with a bucketless system where mop covers are either pre-wetted with the cleaning or rinsing solutions, or the operator sprays the mop covers with a cleaning solution after the covers have been placed on the mop head. The mopping should be done in linear overlapping strokes from clean to dirty, dry to wet, the same procedure that is recommended for wiping. In a cleanroom, the corners furthest away from the entry doors are usually the cleanest areas since they have the least foot traffic. Aisles and entry doors sustain the greatest traffic and are usually the dirtiest areas. So mopping is done from far corners to aisles and entry doors (cleanest to dirtiest). Swabs wetted with a cleaning solution, IPA, or sterile water can be used to address very tight areas. Some possible candidotes for swab cleaning are: vents in the back wall or front surface, the junction of the walls with the floor and ceiling of the cabinet, surface dimples surrounding rivets or screws, connectors to hoses or filters, etc.

All surfaces ore cleaned with a multi-purpose antifungal, antivirucidal and antibacterial agent daily.

Wipers are discarded ofter one use. If cleaning tools are reused, their cleanliness is mointained by thorough rinsing and sanitization or cleaning and outoclaving after use and by storing in a cleon environment between uses.

Trash receptocles should be emptied daily or more frequently according to the needs of the area. Trash should be collected in suitable plastic bags and removed with minimal agitation.

Supplies, if appropriate, and equipment to be placed in the buffer or clean room environment or isolator, must be unpockaged in the anteroom area and wiped with a sanitizing agent, such as sterile 70% isopropyl alcohol. Alternatively, if supplies are planned to be received in sealed pouches, the pouches can be removed as the supplies are introduced into the buffer or clean area without the need to sanitize the individual supply items.

No shipping or other external cartons (e.g., corrugated cardboard) moy be taken into either the buffer or ante room areas.

Disinfectants should be alternated periodically to prevent the development of resistant organisms.

Problems with equipment (burned out lights, computer malfunctions, laminar flow hood problem, etc.) should be reported to the Pharmacist in Charge.

Autoclave should be cleaned weekly per manufacturer with approved cleaning agent.

Refer to rotation schedule for specifics on cleaning

TRAINING

Training, based on written protocols, is essential for proper cleaning of a cleanroom. Cleanroom personnel are assigned responsibilities. Cleaning logs with check-offs for daily, weekly, and monthly cleaning are completed by the responsible personnel.

Personnel are trained using these SOPs, and then tested to ensure proficiency in cleaning and maintenance procedures. Personnel is retrained on a regular schedule. The PIC shall ensure training is completed and will ensure audits are completed when necessary.

Version # 006.001

Clean Room Material Washing

	Name	*Signature*	*Date*
Pharmacist-In-Charge			
Employee Signature of Acceptance:			

POLICY:

This policy describes the process of washing reusable materials.

PURPOSE:

All reusable materials (beakers, spin bars, etc.) shall be thoroughly and completely cleaned following use in compounding and prior to depyrogenation/sterilization (if applicable). Thorough cleaning shall be done to prevent the possibility of cross-contamination of CSPs.

RESPONSIBILITY:

The pharmacist-in-charge and sterile compounding supervisor are responsible to ensure that this procedure is followed.

PROCEDURE:

Initial cleaning shall be done using an appropriate low residue detergent with thorough scrubbing and rinsing. Particular attention should be given to difficult to remove preparations (i.e. oils, high active concentrations, etc.) and areas of the material that might be difficult to clean (lip of beaker, spout of beaker, crevices, etc.). Several rounds of detergent use and rinsing may be necessary to achieve completely clean materials. Initial cleaning and rinsing is critical to ensuring that reusable materials do not pose a cross-contamination risk and that they are maintained in an acceptable condition. During depyrogenation/sterilization, left-over residues can be burned onto the surface of materials, creating unacceptable conditions for re-use os they pose contamination risks in addition to appearing insanitary.

Notify the pharmacist-in-charge immediotely if any equipment has a stain or substance that is not removed after multiple cleaning attempts.

Once materials are cleaned thoroughly and all detergent residues removed, materials shall be rinsed briefly with sIPA.

Following sIPA rinse, materials shall be rinsed with sterile water. Materials shall then be placed on the drying rack and allowed to dry completely.

Materials shall then be placed on the drying rack and allowed to dry completely. Monthly visual inspections of all reusable materials will be performed by the pharmacist-in-charge or sterile compounding supervisor.

Version # 008.001

Autoclave Procedures

	Name	*Signature*	*Date*
Pharmacist-In-Charge			
Employee Signature of Acceptance:			

Policy:
This procedure describes the process of steam sterilization.

Purpose:
This procedure describes the process of steam sterilization and the required actions to be taken to ensure that steam sterilization occurs in a correct and repeatable manner that ensures that appropriate sterilization has occurred.

Responsibility:
The pharmacist-in-charge and sterile compounding supervisor are responsible for ensuring that this procedure is followed.

Procedure:
Steam sterilization shall occur in a consistent, correct, and repeatable manner to ensure that components, materials, and compounded preparations are properly sterilized.

Prior to steam sterilization, components, materials, and compounded preparations shall be prepped or compounded according to procedure.

Prepped components and materials shall be placed in appropriate autoclave pouches designed to prevent post-sterilization microbial penetration.

Terminally steam-sterilized compounded preparations shall contain a biological indicator designed to validate steam sterilization cycles in a non-dispensable specimen to ensure that sterilization has occurred.

The autoclave shall be loaded according to manufacturer recommendations with sufficient room for circulation of air within the chamber and around contents.

All cycles shall contain a temperature indicator. Per manufacturer recommendations, each autoclave shall be tested weekly with a biological indicator to verify sterilization capability. Autoclaves used less frequently than weekly shall be tested with a biological indicator on an as needed basis (i.e. with each load).

The autoclave shall be set to sterilize at 121 °C and 15 PSI for 20-60 minutes. Sterilization time for terminally steam-sterilized compounded preparations shall be specified in the compounding record.

Steam sterilization cycles shall be documented on the autoclave batch log. Personnel responsible for loading and unloading the autoclave shall document the following information for each load:

- *Date*
- *Load #*
- *Description of Contents or Compound Name/Lot #*
- *Start Settings*
- *Start Time*
- *Start Operator Initials*
- *Final Display Description (i.e. CYC FINISH)*
- *Steam Strip Results*
- *End Settings*
- *End Time*
- *Remove Operator Initials*

Personnel who remove autoclave contents shall ensure that all components and materiols are clearly marked with the load number and expiration date. An expiration date of 30 days shall be assigned to all components and moterials which are stored prior to use.

Biological indicators shall be incubated per manufacturer recommendations and results recorded to verify that sterilization has occurred.

Depyrogenation and Dry Heat Sterilization Procedures

	Name	*Signature*	*Date*
Pharmacist-In-Charge	*Nick Kirkpatrick, PharmD*		
Employee Signature of Acceptance:			

POLICY:

Depyrogenation and dry heat sterilization procedures utilized in the pharmacy.

PURPOSE:

To ensure proper controls and monitoring are in place to sterilize equipment and preparations using dry heat sterilization.

RESPONSIBILITY:

The pharmacist-in-charge is the responsible person to assure that this procedure is followed.

PROCEDURE:

Purpose: *Depyrogenation of glassware and other reusable materials prior to use ensures minimal endotoxin content of final compounded preparations.*

Responsible: *The PIC is responsible for ensuring that sterile compounding pharmacists and sterile compounding technicians complete this procedure.*

Procedure:

Oven trays for depyrogenation and dry heat sterilization will be stored and used separately for their identified use.

Glasswore and metal devices sholl be cleaned prior to depyrogenotion in accordance with the Material Cleaning and Washing pracedure.

Glass and metal devices shall be covered tightly ond wrapped with foil and then exposed to dry heat in on oven at a mean temperature ***of 250◦C for 45 minutes*** *to achieve depyrogenation. Exposure time shall not be started until the oven has reached the desired temperature. Vials will be rinsed with SWFI after oven depyrogenotion.*

Depyrogenation completion sholl be documented on the apprapriate oven batch log.

An expiration date of 30 days after depyrogenation shall be assigned to all glassware and metal devices which are stored prior to use. Any glassware or metal devices which have reached expiration shall be depyrogenated and ossigned a new expiration date.

Validation of depyrogenation shall occur every 6 months. Validation shall demonstrate a minimum 3 log reduction in endotoxin.

Compounded Preparation Using Dry-Heat Sterilization

1. *When possible, compounded preparations should be filtered through a 1 um particulate filter prior to filling. Vials shall be placed onto trays and placed in oven with sufficient room for air to circulate over the entire surface of the container. Temperature Indicator strips and biological indicators are placed in the oven. Biological indicators shall be placed in non-dispensable specimens to ensure sterilization of the CSP.*
2. *Oven will be set to sterilize for three hours at 311 degrees F (160 degrees C), unless otherwise recommended. The fan must be on to ensure that air is properly circulated throughout the chamber during sterilization.*
3. *All dry-heat sterilization runs will be logged to track date, load number, contents, temperature, settings, times, test results and operator.*
4. *All sterilized preparation (s) will be stored in a separate area designated for sterile preparation only.*

Version # 018.001

Hand Hygiene Procedure

	Name	*Signature*	*Date*
Pharmacist-In-Charge			
Employee Signature of Acceptance:			

Proper hand hygiene is critical to contamination control. Personnel are a major source of contamination and appropriate hand hygiene can help reduce bioburden and the possibility of contamination. Hand hygiene should be performed in the following manner in the dedicated area at the appropriate time during the garbing process:

1. *Fingernails should be kept short, clean, and natural.*
2. *Remove debris from underneath fingernails with a disposable nail cleaner and warm water.*
3. *Wash hands and forearms to the elbow for at least 30 seconds with antimicrobial soap and water. Hand washing should be vigorous and thorough, paying careful attention to frequently missed areas (i.e. tips of fingers, thumb, in between fingers)*
4. *Rinse well in warm water at an adequate flow rate. Water should flow from fingertips to elbows and drain into the sink. Be sure to remove all soap from skin.*
5. *Carefully dry hands and arms with a lint-free towel.*
6. *Cantinue with garbing per protocol.*

Wickliffe Pharmaceuticals, Inc.

d/b/a Wickliffe Veterinary Pharmacy

Aseptic Compounding Environment

	Name	*Signature*	*Date*
Pharmacist-In-Charge			
Employee Signature of Acceptance:			

USP chapter <797> sterile preparation compounding is performed in designated areas only.

The air entering a cleanroom from outside is filtered to exclude dust, and the air inside is constantly recirculated through high efficiency particulate air (HEPA) and/or ultra low particulate air (ULPA) filters to remove internally generated contaminants. These filtration systems keep the air changes appropriate at all times.

Staff members enter and leave through one air locked door. All cleanroom doors are wired into an antilock system preventing more than one to be opened at any given time. Only in the event of a fire, will the cleanroom doors be allowed to be opened simultaneously. This system allows minimal contamination by dust and other particles. Staff wear protective clothing such as hairnets, face masks, gloves, show covers and lab coats. All protective clothing is classified for use in ISO 7 and ISO 5 environments, depending on the orea in which the staff will be compounding. Appropriate garb is donned in the cleonroom ot all times. Upon entry in the garbing area, staff is required to put on the appropriate cleanroom attire. The use of appropriate cleanroom attire minimizes the contamination by personnel in the cleanroom area.

Only trained personnel are allowed in the cleanroom. No persons may pass into the designoted garbing area unless they are one of the cleanroom staff. This minimizes interruption and contamination.

Equipment inside the cleanroom is designed to generate minimal air contamination. Cleanroom furniture is also designed to produce a minimum of particles and to be easy to clean.

The cleanroom is kept at a positive pressure so that if there are any leaks, air leaks out of the chamber instead of unfiltered air coming in.

The cleanroom HVAC systems controls the temperature and the humidity.

Sterile compounded preparations shall be compounded in accordance with the aseptic processes and in an area separate and distinct from the area used for the compounding of non-sterile products. Chemicals are opened only in designated areas. Powder containment hoods are provided for the accurate and safe weighing of chemicals. They provide protection for the compounder as well as prevent

cross contamination and environmental contamination. No more than one chemical may be opened at any given time while under the compounding hood.

The areas used for compounding are maintained in clean, orderly, and sanitary conditions.

The areas for drug compounding shall be maintained in a good state of repair. The plumbing system shall be free of defects that could contribute to contamination of any compounded product. Adequate washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but not be limited to, hot and cold water, soap or detergent, antibacterial hand sanitizer and single-use aseptic wipes.

The area for compounding provides adequate lighting and ventilation.

The area for compounding is free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a sanitary and timely manner.

Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored as directed by the manufacturer, or according to USP monograph requirements, in a clean, dry area, under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer). Shelving units are provided for the storage of all chemicals. Chemicals shall be stored in a manner such that they are protected from contamination. All containers shall be properly labeled.

Wickliffe Pharmaceuticals, Inc. d/b/a
Wickliffe Veterinary Pharmacy

Shipped/Delivered Compounded Preparations

	Name	*Signature*	*Date*
Pharmacist-In-Charge			
Employee Signature of Acceptance:			

POLICY:

Prescription orders are delivered/shipped to clients through UPS.

PURPOSE:

The purpose of this policy is to establish and describe the activities involved in the shipping of medications to clients. The objective of the Shipping Department is to ensure that the client receives the correct compounded preparation in a way that prevents damage or tampering and arrives in an organized and timely manner.

RESPONSIBILITY:

The Shipping Representative, Pharmacist(s) and Director of Pharmacy.

PROCEDURE:

- *All prescription orders are verified and checked for accuracy and completeness by a pharmacist. Once checked and verified, the order is given to the Shipping Department for shipping.*
- *When preparations are dispensed to locations outside the premises in which they are compounded, compounding personnel shall select packing containers and materials that are expected to maintain physical integrity, stability, and sterility (if needed) of preparation during transit. Packing shall be selected that simultaneously protects preparations from damage, leakage, contamination, and degradation and protects personnel who transport packed preparation.*
- *Based on the size and volume of the order, the Shipping Department will determine the most appropriate form of packaging and shipping mode. Compounded preparation containers must be protected by using either bubble wrap, paper wrap, air packets, shipping paper or Styrofoam pellets. Cold preparations require a designated shipping box, cold packs and insulated aluminum bags. All cold preparations are maintained at refrigerated temperatures until UPS picks up the package. All cold preparations are shipped overnight.*
- *The Shipping Representative is responsible for checking the pick-ticket against the preparations accompanying the pick-ticket. The shipping representative is responsible for entering the correct client's address and entering the correct shipping method. The shipping representative is responsible for making sure the box/package is properly sealed.*

Shipped/Delivered Compounded Preparations

- *Temperature verification of room temperature and refrigerated packages shall be performed twice yearly during peak hot and cold seasons to simulate worst case conditions. Excursions between 15°C and 30°C (59° and 86°F) during shipping are allowed, provided the mean kinetic temperature does not exceed 25°C (77°F). Transient spikes up to 40°C (104° F) are permitted as long as they do not last for more than 24 hours. Spikes above 40°C (104° F) may be permitted if the manufacturer states it's acceptable.*
- *Pick-up prescriptions are placed on the designated pick-up shelf within the pharmacy. They are retrieved by the receptianist when the client arrives for pick-up.*
- *Cold pick-up prescriptions are placed in the designated pick-up refrigerator within the pharmacy. They are retrieved by the receptionist when the client arrives for pick-up.*
- *All packages that are shipped have a tracking number and shipping date that can be easily traced. Shipments are signed for upon arrival. UPS is required to notify Wickliffe immediately, should o package become damaged or lost. Damaged or lost packages are investigated and replaced when necessary.*

Wickliffe Pharmaceuticals, Inc. d/b/a
Wickliffe Veterinary Pharmacy

Packing & Shipping

Pharmacist-In-Charge	*Name*	*Signature*	*Date*
Emplayee Signature af Acceptance:			

POLICY:

Prescription orders are delivered/shipped to clients through UPS.

PURPOSE:

The purpose of this policy is to establish and describe the activities involved in the packing of medications to clients. The objective of the Shipping Department is to ensure that the client receives the correct medication in a way that prevents damage or tampering and arrives in an organized and timely manner. ALL medications are prioritized by request, urgency, and any other form of request that a patient or practitioner has requested. This is done as the prescription is taken and verified by the pharmacist. Order entry pick route in which shipped EA: overnight, ground etc. The shipping Representative notifies customer service representative if a shipment has been delayed past a request date. It is the responsibility of the customer service technician to relay information as to a delay of a requested shipment.

RESPONSIBILITY:

The Shipping Representative, Pharmacist(s).

PROCEDURE:

All prescription arders are verified and checked for accuracy and completeness by a pharmacist. Once checked and verified, the order is given to the Shipping Department for shipping. Based an the size, volume of the order, and destination location, the Shipping Department will determine the most appropriate farm of packaging, shipping mode, and UPS shipping account. Product containers must be protected by using either bubble wrap, air packets, shipping paper or Styrofaam pellets. The Shipping Representative is responsible for entering the correct client's address and making sure the box/package is properly sealed with no identifying labels/wording to indicate that the package/box is originating from a pharmacy. All packages have a tracking number and shipping date that can be easily traced.

Packing the product:

a. *Verify each item on the pick ticket is in the basket. Check details on label compared to pick ticket. Initial beside each item once checked.*
b. *All suspensions get an adapter cap and syringe. 30ml to 240ml bottles get a small adapter cap. 300ml bottles and larger get a large adapter cap. Syringe sizes are based on each product. All*

Packing & Shipping

syringes, adapter caps, and scoops should be in a plastic bag for shipping provided by the pharmacist.

c. *Check the address and who it is shipping to and decide if they can receive a Wickliffe monthly special sheet. Vets & hospitals can receive specials sheet. If the address is different, no special sheet is to be placed in the box.*
d. *Packing boxes:*
    a. *Put paper on bottom of box, item(s), paper on top filled to the top. (Closing the box should require a little pushing to ensure products are packed tightly.)*
    b. *Injectables:*
        i. *100ml-individually wrapped in bubble bags if less than 6 bottles in order. If 6 or more bottles, pack in divider box with peanuts used as filler to keep bottles from moving. Then put the divider box inside a bigger box for shipping surrounded by peanuts on all sides.*
        ii. *30ml-can put up to 3 bottles lying on side in 1 bubble bag. Fold top of bag over to seal so the bottles are tight in the bag.*
        iii. *50ml- individually wrap in bubble bags.*
        iv. *10ml-can put up to 6 bottles in one bag. Fold top of bag over to seal so the bottles are tight in the bag.*
        v. *All bubble wrapped injections should be wrapped individually in paper and placed in box on top of paper in bottom and covered with poper on top and on sides. Make sure no bottles are touching the outside of the box.*
    c. *Powder jors should be stacked neatly in box on top of a layer of paper ond filled in with peanuts to keep jars from knocking into each other during shipment.*
    d. *Cold Products ore to be placed inside a plastic bag then put in foil shipper with at least 2 ice packs per product. Then packed in a box with paper on top and bottom. Ploce a "Refrigerate Upon Arrival" sticker on outside of box.*
    e. *Paste tubes should always be in a plastic bog to contain spills.*
e. *Always put heaviest/biggest products on bottom of box.*

Shipping the Packed Product:

a. *Place the packed product on the designated scale that is connected to the UPS WorldShip softwore.*

Packing & Shipping

b. *The product must be shipped on the correct account depending on the size, destination, and shipping speed.*

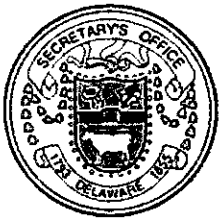
All packages receive a tracking number and at the request can be trocked via UPS website

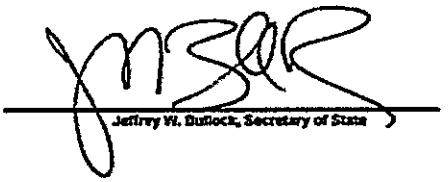
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "WEDGEWOOD VILLAGE PHARMACY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF MARCH, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





5944344 8300

SR# 20241174280

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203115229

Date: 03-26-24

Kentucky Board of Pharmacy

125 Holmes St.
Frankfort, KY 40601

Inspection Report

Pharmacy

Name: *WICKLIFFE LLC* **Permit No.:** *P08205*

Address: *4340 GEORGETOWN ROAD, LEXINGTON, KY 40511*

Phone: *859-389-7470* **Fax:** *859-381-9252* **Email:** *NKIRKPATRICK@WICKLIFFERX.COM*

Current: *Permit,DEA Registration*

Inspection

Date: *05/03/2022* **Time In:** *9:00 AM* **Time Out:** *1:50 PM*

Type: *Routine*

Notes: *Inspection Report 1 of 2: routine inspection*

Pharmacist and Interns

ALEX G DUDLEY
License: *PT00021915* Status: *Declined Renewal* PIC: *No*

Aliona Markos
License: *PT00357969* Status: *Active* PIC: *No*

Emily A Elkins
License: *PT00367878* Status: *Lapsed* PIC: *No*

McKenzie A Winfrey
License: *PT00369249* Status: *Active* PIC: *No*

Jackie S Bernard
License: *PT00088470* Status: *Active* PIC: *No*

BROCK EDMOND LEISGE
License: *018908* Status: *Active* PIC: *No*

Natasha E. Thompson
License: *018196* Status: *Active* PIC: *No*

Tyler M Fint
License: *PT00357870* Status: *Active* PIC: *No*

Emily K Morton

Pharmacist and Interns *(continued)*

License: *PT00375627* Status: *Active* PIC: *No*

Donni J Plunkett

License: *PT00351245* Status: *Active* PIC: *No*

Samantha Briggs

License: *PT00362929* Status: *Active* PIC: *No*

Jate Bernard

License: *PT00358213* Status: *Active* PIC: *No*

REGAN T. WATKINS

License: *I14719* Status: *Intern* PIC: *No*

Alyssa F Morris

License: *PT00375468* Status: *Active* PIC: *No*

Amber N Twisdale

License: *PT00374478* Status: *Active* PIC: *No*

Jessica Crossan

License: *PT00346925* Status: *Active* PIC: *No*

MICHELLE COMPTON

License: *PT00024263* Status: *Active* PIC: *No*

Britney Gavenonis

License: *PT00370317* Status: *Active* PIC: *No*

Nathaniel C Justice

License: *PT00371651* Status: *Active* PIC: *No*

Rachael Shumway

License: *PT00369251* Status: *Active* PIC: *No*

Khila A Harris

License: *PT00357204* Status: *Active* PIC: *No*

NICHOLAS R. KIRKPATRICK

License: *018695* Status: *Active* PIC: *Yes*

ANTHONY W PIZZINO

License: *PT00370411* Status: *Active* PIC: *No*

Grace A Bentley

Pharmacist and Interns *(continued)*

License: *PT00370233* Status: *Active* PIC: *No*

Alyssa N Johnson

License: *PT00119675* Status: *Lapsed* PIC: *No*

TAREK IBRAHIM KHALID

License: *I15729* Status: *Intern* PIC: *No*

CHRISTOPHER BROOKS HOGUE II

License: *017869* Status: *Active* PIC: *No*

Emily Rojas

License: *PT00374884* Status: *Active* PIC: *No*

Pharmacy Area

Reference Material (201 KAR 2:090) Section 1	*Compliant*
Equipment (201 KAR 2:090) Section 2	*Compliant*
Security and Control (201 KAR 2:100)	*Compliant*
Sanitation (201 KAR 2:180)	*Compliant*
Refrigeration (201 KAR 2:090) Section 2 (1)(h)	*Compliant*
Drug Storage (201 KAR 2:180) Section 5	*Compliant*
Exclusive Compounding Area (KRS 217.055(2)) 201 KAR 2:180 Section 1	*Compliant*

General

Valid R.Ph License Displayed (KRS 315.110) (2)	*Compliant*
Valid Pharmacy Permit (KRS 315.035) and KRS 315.020 (add PIC info)	*Compliant*
Valid Intern Registration Identification Card (201 KAR 2:040) Section 4	*Not Inspected*
Valid Technician Registration Displayed: KRS 315.138 (2)	*Compliant*
Records/Computer Records (201 KAR 2:170)	*Not Inspected*

Comments

The system shall have the capability of producing a hard-copy printout of all original and refilled prescription data as required in Section 1 of 201 KAR 2:271

General *(continued)*

Syringe/Needle Register (KRS 217.177)	*N/A*
Outdated Stock Removed (KRS 217.055)	*Compliant*
Prescription Labeling Requirements (KRS 217.065)	*Compliant*
Pseudoephedrine Log (KRS 218A.1437) KRS 218A. 1446	*N/A*
Collaborative Care Agreements (201 KAR 2:220)	*N/A*
Board Authorized Protocols (201 KAR 2:380)	*N/A*

Generic Substitution

Additional Prescription Recordkeeping (KRS 217.822) and 201 KAR 2:280	*Not Inspected*
Generic Drug Sign Posted (KRS 217.830)	*Compliant*
Pamphlet (KRS 217.896)	*Not Inspected*

Controlled Substances

CII Prescription Requirements (KRS 218A.180) and 902 KAR 55:105	*N/A*
Oral CIII-V Prescription Requirements (KRS 218A.180) and 902 KAR 55:105	*Compliant*
Written CIII-V Prescription Requirements (KRS 218A.180) and 902 KAR 55:105	*N/A*
Purchase Records/DEA 222 Forms (KRS 218A.200)	***Noncompliant***

Comments

201 KAR 2:311 Section 2. A compounded drug containing a controlled substance shall only be compounded for patient specific dispensation from the pharmacy to the ultimate user.

KASPER (902 KAR 55:105, 110)	*N/A*
CII-V Filing Requirements - Prescription/Po: 21 (CFR 1304.04)	*Compliant*
Exempt CV Register (KRS 218A.190)	*N/A*
Biennial Inventory Complete (21 CFR 1304.11) and KRS 218A. 200 (7)	*Compliant*

Comments

12/21/21 End of Day

Controlled Substances *(continued)*

Power-of-Attorney Current 21 (CFR 1305.05)	*N/A*
Inform Public of Proper and Safe Disposal of Controlled Substances (KRS 218A.170(3)(4))	*N/A*

Patient Records/Counseling

Patient Record System (201 KAR 2:210)	*Compliant*
Patient Recordkeeping (201 KAR 2:210)	*Compliant*
Drug Utilization Review (201 KAR 2:210)	*Compliant*
Patient Counseling (201 KAR 2:210)	*Not Inspected*
Refused Offers Documented (201 KAR 2:210)	*Not Inspected*

Inspector's Signature

I have completed this inspection in accordance with the statutes and administrative codes.



Inspector: *Jessica Williams*

Pharmacist's Signature

I have read and understand the statutes and administrative codes. I acknowledge that the items noted in this report have been discussed with me. I understand that if I disagree with any of the deficiencies cited, that I have the right to refute them on this report or and other form that I choose to send to the department.



Pharmacist: *Nick Kirkpatrick*

Kentucky Board of Pharmacy

125 Holmes St.
Frankfort, KY 40601

Report

Pharmacy

Name: *WICKLIFFE LLC* **Permit No.:** *P08205*

Address: *4340 GEORGETOWN ROAD, LEXINGTON, KY 40511*

Phone: *859-389-7470* **Fax:** *859-381-9252* **Email:** *NKIRKPATRICK@WICKLIFFERX.COM*

Inspection

Date: *05/03/2022* **Time In:** *9:00 AM* **Time Out:** *1:50 PM*

Type: *Routine*

Notes: *Inspection Report 2 of 2: sterile compounding*

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Pharmacist and Interns *(continued)*

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License: *017869*	Status: *Active*	PIC: *No*
Emily Rojas		
License: *PT00374884*	Status: *Active*	PIC: *No*

Policies and Procedures

Compounding Personnel Education and Assessment	*Compliant*
Personnel Cleansing and Garbing	*Compliant*
Cleaning and Disinfecting Compounding Area	*Compliant*
Operation of Isolators	*Compliant*
Compounding Procedures for In-Process Checks and Final Product Verification	*Compliant*
Ingredient Inspection and Assessment	*Compliant*
Checks for Compounding Accuracy and Recordkeeping of Compounding Log	*Compliant*
Physical Inspection of CSPs	*Compliant*
Final Check of CSPs Including Labeling	*Compliant*
Maintenance and Assessment of Compounding Equipment	*Compliant*
Assignment of BUDs	*Compliant*
Monitoring of Storage Areas	*Compliant*
Packaging, Handling, Security, Storage, Disposal, Destruction, Transport and Return of CSPs and Supplies	*Compliant*
Quality Assurance Program	*Compliant*
Adverse Events Reporting and Monitoring	*Compliant*
Hazardous and Oncology Drug Handling and Disposal	*Compliant*
Sterilization by Steam	*Compliant*

Policies and Procedures *(continued)*

Sterilization by Dry Heat	*Compliant*
Depyrogenation by Dry Heat	*Compliant*
Monitoring of CSPs Dispensed Prior to Sterility Results, including Recall Procedures	*Compliant*
P&P reviewed and revised annually	*Compliant*

Comments

transitioning P&Ps to electronic-based system

Training and Garbing

Documentation all compounding personnel passed initial and annual/semi-annual written exam for appropriate risk level for cleaning and disinfecting.	*Compliant*
Documentation all compounding personnel passed initial and annual/semi-annual written exam for hand hygiene and garbing.	*Compliant*
Documentation all compounding personnel passed initial and annual/semi-annual written exam for aseptic technique.	*Compliant*
Visually observed and appropriately documented competencies of cleaning and disinfecting, initially and at the completion of media fill test, and including environmental services, if applicable and when appropriate.	*Compliant*
Visually observed and appropriately documented competencies of hand hygiene and garbing, initially with initial gloved fingertip sample with zero growth.	*Compliant*
Visually observed and appropriately documented competencies of hand hygiene and garbing annually/semi-annually done upon completion of aseptic media fill test performed annually/semi-annually with up to 3 total CFUs.	*Compliant*
Visually observed and appropriately documented competencies of aseptic technique, initially and annually/semi-annually for appropriate risk level under most challenging conditions.	*Compliant*
Training of any equipment used.	*Compliant*
Documentation of immediate reinstruction, reevaluation and retesting of compounding personnel who fail any testing.	*Not inspected*
Written policy personnel cannot compound if have sunburn, illness, open sores, etc.	*Compliant*
Personnel remove outer garments, make-up, visible jewelry (hand, wrist, ears, lips, eyebrow piercings).	*Compliant*
Personnel keep nails short and natural.	*Compliant*

Garbing

Garb from dirtiest to cleanest, using the line of demarcation appropriately.	*Compliant*
Performs hand washing appropriately up to the elbows for 30 seconds and uses a nail pick.	*Compliant*
Use waterless, alcohol based surgical scrub with persistent activity. Has chlorhexidine/emollients: Purell Surgical Scrug; Avagard; Sterillium; Surgicept; Triseptin; Alcare.	*Compliant*
Sterile gloves donned appropriately.	*Compliant*
Dispose of gown when leave compounding area or reuse for one shift (nonhazardous).	*Compliant*
Non-garbed personnel are not entering compounding area.	*Compliant*

Environment with Ante and Buffer Rooms

Floor is smooth, impervious, free from cracks and crevices, and seams are heat sealed.	*Compliant*
Comments *Observation by inspector: Floor in buffer room extremely slippery*	
Ceiling tiles are sealed, free from cracks and crevices, and seams where walls and ceiling meet are sealed.	*Compliant*
Walls are painted with epoxy based paint or other impermeable surface, are smooth, impervious, easily cleanable, and free from cracks and crevices, seams are heat sealed.	*Compliant*
Non-shedding equipment is used.	*Compliant*
Limited entry to necessary personnel.	*Compliant*
Accessories: shelving, chairs, stools, carts easily cleanable and non-permeable, free from cracks and crevices, low particulate generating and limited to necessary equipment in ante and buffer rooms.	*Compliant*
All items cleaned and disinfected before bringing into buffer room.	*Compliant*
Ante Room has a sink with hot and cold water and hands dried with lint free non-shedding, disposable paper towels or blow dryer.	*Compliant*
Buffer Room has no sink, drain or water source.	*Compliant*
Proper utilization of line of demarcation (LOD).	*Compliant*
HEPA Filters must be on air ducts in the ceiling of ante and buffer rooms.	*Compliant*
Food, drinks, gum prohibited in compounding area.	*Compliant*
If LAFW Blower turned off, must run for 30 minutes before using.	*Not inspected*

Environment with Ante and Buffer Rooms *(continued)*

If no physical barrier between the buffer and ante rooms, only performing low and medium risk sterile compounding.	*N/A*
If no physical barrier between the buffer and ante rooms, air velocity is at least 40 feet/minute continuously from buffer area across LOD into ante area.	*N/A*
If no physical barrier between the buffer and ante rooms, air velocity is recorded every shift, a minimum of daily.	*N/A*
Pressure is recorded each shift, a minimum of daily.	*Compliant*
Ante room is positive pressure of at least 0.02 inch water column to general pharmacy.	*Compliant*
Buffer room is positive pressure of at least 0.02 inch water column to ante room.	*Compliant*
Temperature is recorded daily.	*Compliant*
Temperature of buffer room is appropriate.	*Compliant*
Controlled storage areas for room temperature is 68 to 77 F or 20 to 25 C.	*Compliant*
Controlled storage area for cold temperature is 36 to 46 F or 2 to 8 C.	*Compliant*
Controlled storage area for freezer temperature is -13 to 14 F or -25 to -10 C.	*Compliant*
Components store in appropriate humidity, recommended 35% to 60%.	*Compliant*

Cleaning

Personnel appropriately garbed when cleaning.	*Compliant*
Cleaning and disinfecting agent (may be one step cleaning and disinfecting) appropriate for bacteria, viruses, fungi.	*Compliant*
Cleaning equipment is non-shedding, disposable or dedicated.	*Compliant*
Daily cleaning of compound area takes place when no compounding is occurring and includes easily cleanable surfaces including counter tops, pass through, etc. and floors.	*Compliant*
Monthly cleaning of compound area takes place when no compounding is occurring and includes everything in compound area – bins, equipment, ceiling, walls and floor.	*Compliant*
Cleaning of ISO Class 5 PEC is documented each shift, a minimum of daily.	*Compliant*
Uses low linting towels to clean ISO Class 5 PEC.	*Compliant*
Uses germicidal detergent diluted with sterile water if not ready to use, to clean each shift or daily.	*Compliant*

Cleaning *(continued)*

ISO Class 5 PEC is disinfected between compounding activities.	*Compliant*
ISO Class 5 PEC is wiped with sterile water followed by disinfectant after spills or surface contamination.	*Not inspected*
70% sIPA allowed to remain in contact with surface for 30 seconds before compounding.	*Not inspected*
PEC cleaned in correct order of top ,back, sides, racks/poles, items on deck, deck.	*Compliant*

Environmental Monitoring: Certification of Ante and Buffer Rooms

All ISO Class 5 PEC and ISO Class 7 and/or ISO Class 8 rooms have been certified as required.	*Compliant*
Review report from certifier. Date: *01/18/2022* Certifier: *Air Source*	*Compliant*
Certification done to CETA guidelines, CAG-003-2006, or similar.	*Compliant*
Certifier's equipment calibrated to manufacturer standards.	*Compliant*
Ante room has HEPA filtered air certified to ISO Class 8 for non-hazardous compounding.	*N/A*
Ante room has HEPA filtered air certified to ISO Class 7 for hazardous compounding.	*Compliant*
Buffer room has HEPA filtered air certified to ISO Class 7.	*Compliant*
ISO Class 7 ante room, minimum of 30 ACPH. ACPH: *38*	*Compliant*
ISO Class 8 ante room, recommended 20 ACPH. ACPH:	*N/A*
ISO Class 7 non-hazardous buffer room, minimum of 30 ACPH with at least 15 from outside source. ACPH: *53*	*Compliant*
ISO Class 7 hazardous buffer room, minimum of 30 ACPH. ACPH: *97*	*Compliant*
Smoke test performed in PEC in direct compounding area to demonstrate unidirectional airflow under dynamic conditions.	*Compliant*
Differential pressure measured to be at least positive 0.02 inch water column from ante room to general pharmacy with door closed.	*Compliant*
Differential pressure measured to be at least positive 0.02 inch water column from buffer room to ante room with door closed.	*Compliant*

Environmental Monitoring: Certification of Ante and Buffer Rooms *(continued)*

Differential pressure measured to be at least negative 0.01 inch water column from buffer room to positive pressure ISO 7 ante room with door closed.	*Compliant*
If no physical separation of ante and buffer room, displacement airflow measured requiring air velocity of 40 feet/minute or more from buffer area across LOD into ante room.	*N/A*
ISO Class 5 areas not more than 3,520 particles per cubic meter of air, taken under dynamic conditions.	*Compliant*
ISO Class 7 areas not more than 352,000 particles per cubic meter of air, taken under dynamic conditions.	*Compliant*
ISO Class 8 areas not more than 3,520,000 particles per cubic meter of air, taken under dynamic conditions.	*N/A*
Room HEPA filters leak tested and repaired if needed.	*Compliant*
PEC HEPA filters leak tested and repaired if needed.	*Compliant*
PEC airflow velocity measured.	*Compliant*
Documentation of viable air and surface sampling shall include date and time of sampling.	*Compliant*
Documentation of viable air and surface sampling shall include sampling shall include sample locations.	*Compliant*
Documentation of viable air and surface sampling shall include method of collection.	*Compliant*
Documentation of viable air and surface sampling shall include frequency of sampling.	*Compliant*
Documentation of viable air and surface sampling shall include volume of air sampled.	*Compliant*
Documentation of surface sampling shall include size of surface sampled, 24-30 cm2.	*Compliant*
Documentation of viable air and surface sampling shall include time of day in relationship to compounding.	*Compliant*
Documentation of viable air and surface sampling shall include action levels.	*Compliant*
Viable air sampling performed using active impaction device with appropriate growth media to support bacteria and for high risk compounding fungus, at least every 6 months in all ISO classified areas using 400 – 1000 L of air per sample.	*Compliant*
Viable air microbial action levels for ISO Class 5: 1000 liters > 1 CFU/m3 or 400 liters > 1CFU/m3.	*Compliant*
Viable air microbial action levels for ISO Class 7: 1000 liters, > 10 CFU/m3 or 400 liters, > 4CFU/m3	*Compliant*

Environmental Monitoring: Certification of Ante and Buffer Rooms *(continued)*

Viable air microbial action levels for ISO Class 8: 1000 liters, > 100 CFU/m3 or 400 liters, > 40 CFU/m3	*N/A*
Viable surface sampling performed periodically on direct compounding areas, buffer and ante rooms, pass thru and surfaces likely to be contaminated, as applicable, using media supplemented with neutralizing effects of disinfecting agents (TSA with lecithin & Polysorbate 80) and done at the conclusion of compounding.	*Compliant*
Surface microbial action levels for ISO Class 5, less than 3 CFU/m3.	*Compliant*
Surface microbial action levels for ISO Class 7, less than 5 CFU/m3.	*Compliant*
Surface microbial action levels for ISO Class 8, less than 100 CFU/m3.	*N/A*
All CFUs analyzed down to the genus with mold, yeast, coagulase positive Staph, gram negative rods requiring immediate Investigation.	*Compliant*
Exceeded action levels should prompt a re-evaluation of adequacy of personnel work practices, cleaning, operational procedures and/or air efficiency and require an investigation into the source of contamination.	*N/A*

Environmental Monitoring: Certification of PEC

All ISO Class 5 PECs have been certified as required.	*N/A*
Review report from outside agency.	*N/A*
Certification done to CETA guidelines, CAG-003-2006, or similar.	*N/A*
Certifiers equipment calibrated to manufacturer standards.	*N/A*
Smoke test performed in PEC in direct compounding area to demonstrate unidirectional airflow under dynamic conditions.	*N/A*
Differential pressure measured to be at least 0.02 inches water column from ante chamber to general pharmacy area.	*N/A*
Differential pressure measured to be at least 0.02 inches water column from main chamber to ante chamber.	*N/A*
ISO Class 5 areas not more than 3,520 particles per cubic meter of air, taken under dynamic conditions.	*N/A*
PEC HEPA filters leak tested and repaired if needed.	*N/A*
PEC airflow velocity measured.	*N/A*
Documentation of viable air and surface sampling shall include date and time of sampling.	*N/A*
Documentation of viable air and surface sampling shall include sample locations.	*N/A*

Environmental Monitoring: Certification of PEC *(continued)*

Documentation of viable air and surface sampling shall include method of collection.	*N/A*
Documentation of viable air and surface sampling shall include frequency of sampling.	*N/A*
Documentation of viable air sampling shall include volume of air sampled.	*N/A*
Documentation of surface sampling shall include size of surface sampled, 24-30 cm2.	*N/A*
Documentation of viable air and surface sampling shall include time of day in relationship to compounding.	*N/A*
Documentation of viable air and surface sampling shall include action levels.	*N/A*
Viable air sampling performed using active impaction device with appropriate growth media to support bacteria and for high risk compounding fungus, at least every 6 months in all ISO classified areas using 400 – 1000 liters of air per sample.	*N/A*
Viable air microbial action levels for ISO Class 5: 1000 liters > 1 CFU/m3 or 400 liters > 1CFU/m3.	*N/A*
Viable surface sampling performed periodically on direct compounding areas using media supplemented with neutralizing effects of disinfecting agents (TSA with lecithin & Polysorbate 80) and done at the conclusion of compounding.	*N/A*
Surface microbial action levels for ISO Class 5, less than 3 CFU/m3.	*N/A*
All CFUs analyzed down to the genus with mold, yeast, coagulase positive Staph, gram negative rods requiring immediate investigation.	*N/A*
Exceeded action levels should prompt a re-evaluation of adequacy of personnel work practices, cleaning, operational procedures and/or air efficiency and require an investigation into the source of contamination.	*N/A*

Compounding Procedures

Documentation of equipment maintenance and calibration logs.	*Compliant*
Objects that shed prohibited from buffer room or compounding area of CAI/CACI: pencils, cardboard, paper towels, cotton gauze pads.	*Not inspected*
Comments *no sterile compounding observed during inspection - cleaning of compounding area was observed*	
Essential paper products (syringe overwrap, work records in protective plastic sleeves) are wiped down with 70% sIPA in ante room before bringing into buffer room or before placing in the ante chamber of CAI/CACI.	*Not inspected*
Required supplies wiped down with 70% sIPA (or removing outer wrap) as item introduced into aseptic work space.	*Not inspected*

Compounding Procedures *(continued)*

Syringes, needles, tubing opened only In ISO Class 5 PEC.	*Not inspected*
Personnel use correct aseptic technique, compounding in first air.	*Not inspected*
Personnel routinely inspecting sterile gloves for wear and tear and replace as necessary.	*Not inspected*
Personnel routinely disinfecting sterile gloves with 70% sIPA prior to entering and when re-entering ISO Class 5 area and touching non-sterile objects.	*Not inspected*
Personnel ascertain CSP ingredients are correct by looking at label and doing unit by unit inspection of product before using.	*Not inspected*
Rubber stoppers of vials/bottles and ampules disinfected with 70% sIPA prior to introducing needle/breaking ampule, waiting 10 seconds for 70% sIPA to dry.	*Not inspected*
Contents thoroughly mixed and inspected for particulate matter, incompatibility or other issues.	*Not inspected*
Before dispensing CSP, clarity is visually confirmed. Identity and amounts of ingredients, procedures to prepare, sterilize, and specific release criteria are reviewed to assure accuracy and completeness.	*Compliant*
Opened single dose ampules must be discarded immediately.	*N/A*
Single dose containers opened in worse than ISO Class 5 used within 1 hour then discarded, with time first used/discard time documented on container.	*N/A*
Single dose containers opened in ISO Class 5 used within 6 hours then discarded, with time first used/discard time documented on container.	*Not inspected*
MDV used for 28 days, or as specified by manufacturer, once punctured, with date first used/discard date documented on MDV.	*Not inspected*
Compound record is required.	*Compliant*
Appropriate procedures and packaging followed for each step.	*Compliant*
Pharmacist verification of steps performed by technicians by visual inspection.	*Compliant*
Documentation of compounding accuracy by 2nd person in addition to compounder if more than one person is compounding, to ensure proper measurement, reconstitution, component usage.	*Compliant*
Name and quantity of each component on batch labels.	*Compliant*
Date and time preparation compounded (may be internal reference number) on batch labels.	*Compliant*
Verifying pharmacist identifier on batch labels.	*Compliant*

Compounding Procedures *(continued)*

BUD on batch labels. Cannot use exp/expiration. May use: Use Before/Discard After/Administer By, etc.	*Compliant*
Auxiliary labels, ie packaging and labeling of hazardous CSP, on batch lables.	*Compliant*
Standard label requirements on patient specific labels to include date of dispensing, and pharmacy name, address if CSP will leave the premises.	*Compliant*
Verifying pharmacist identifier on patient specific labels.	*Compliant*
BUD on patient specific labels. Cannot use exp/expiration. May use: Use Before/Discard After/Administer By, etc.	*Compliant*
Flow rate, if applicable, on patient specific labels.	*N/A*
Auxiliary labels, ie packaging & labeling of hazardous CSP, on patient specific labels.	*Compliant*
Directions for use, including infusion rate, on patient specific labels.	*Compliant*
Required controlled substances transfer warnings, where applicable, on patient specific labels.	*Compliant*
Identity of dispensing pharmacist on patient specific labels.	*Compliant*
Storage requirements, when applicable, on patient specific labels.	*Compliant*
If redispense CSPs, must ensure sterility, purity and stability of CSP and BUD cannot be changed unless retested.	*N/A*
Check for container and closure integrity, done after compounding and if stored, before dispensing.	*Compliant*
Compounding accuracy documented by verification of steps.	*Compliant*
Verification of identity and quantity verified by reconciliation of components.	*Compliant*
Labels verified as being correct.	*Compliant*

Continuous Quality Improvement

Share data with staff.	*Compliant*
Track and trend data.	*Compliant*
Track complaints from patients and practitioners.	*Compliant*
Formalized in writing.	*Compliant*

Continuous Quality Improvement *(continued)*

Consideration of all aspects of preparation and dispensing including environmental testing and verification of results.	*Compliant*
Description of specific monitoring and evaluation activities.	*Compliant*
Specification of how results are to be reported and evaluated.	*Compliant*
Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded.	*Compliant*
Delineation of the individuals responsible for each aspect of the program.	*Compliant*

Sterile Compounding of Hazardous Drugs

Personnel who handle, dispose or compound HD are trained and competency is assessed prior to handling HD and annually thereafter. Training shall be a didactic overview and verified by testing specific HD preparation techniques.	*Compliant*
Personnel who compound HD shall be trained in storage, handling and disposal.	*Compliant*
Personnel who compound HD shall be trained in safe aseptic manipulation practices.	*Compliant*
Personnel who compound HD shall be trained in negative pressure techniques when utilizing BSC or CACI.	*Compliant*
Personnel who compound HD shall be trained in correct use of Closed-System Transfer Devices (CSTD), if applicable.	*N/A*
Personnel who compound HD shall be trained in containment, cleanup and disposal for breakages and spills.	*Compliant*
Personnel who compound HD shall be trained in treatment of personnel contact and inhalation exposure.	*Compliant*
Written confirmation by all compounding personnel of reproductive capability that they understand the risks of handling HD.	*Compliant*
HD are handled with caution at all times using chemo rated gloves during receiving, distributing, stocking, inventorying, preparing for administration, and disposal.	*Not inspected*
Personal compounding equipment (PPE) includes gowns with low permeability like polyethylene.	*Not inspected*
Personal compounding equipment (PPE) includes face masks.	*Not inspected*
Personal compounding equipment (PPE) includes eye protection, as appropriate.	*Not inspected*
Personal compounding equipment (PPE) includes hair covers.	*Not inspected*
Personal compounding equipment (PPE) includes shoe covers or dedicated shoes.	*Not inspected*

Sterile Compounding of Hazardous Drugs *(continued)*

Personal compounding equipment (PPE) includes double gloving with chemo rated gloves, with outer glove being sterile.	*Compliant*
HD CSP are compounded in a BSC or CACI.	*Compliant*
BSC or CACI is located inside an ISO Class 7 area that is physically separate from other areas and is negative pressure of 0.01 inch water column to adjacent positive pressure ISO Class 7 ante room.	*Compliant*
Documentation from CACI manufacturer that the ISO Class 5 environment is maintained under dynamic conditions when not located in an ISO Class 7 environment but must be in a negative pressure room with at least 12 ACPH.	*N/A*
For low volume exemption, defined by KBOP as 5 HD CSPs/2 week period, may use 2 levels of containment.	*N/A*
Documentation from manufacturer of recovery time to achieve ISO Class 5 air quality of CACI when turning off/on and when transferring material from ante chamber to main chamber before and during compounding.	*Not inspected*
CACI located in low traffic area.	*Compliant*
For CACI, pressures recorded each shift, minimum of daily. Main chamber is at least negative 0.01 inch water column to ante chamber and ante chamber is at least positive 0.02 inch water column to general pharmacy.	*Compliant*
PEC cleaned daily/each shift in correct order of top, back, sides, racks/poles, front inside of BSC shield or CACI, gauntlets in CACI, items on deck, deck, CACI ante chamber in the same order,	*Compliant*
HD shall be stored separately from other inventory.	*Compliant*
HD disposed of in a manner that complies with all Federal and State laws.	*Not inspected*

12 Hour BUD

Compounded in an ISO Class S LAFW not located in ISO Class 7 room.	*N/A*
Low risk, non-hazardous, patient specific CSP.	*N/A*
BUD 12 hours or less, administration begins no later than 12 hours from beginning of compounding.	*N/A*
Personnel gowns and garbs the same as for a clean room.	*N/A*
Cleaning of ISO Class 5 LAWF is the same as for an ISO Class 5 LAWF in clean room.	*N/A*
ISO Class 5 LAWF is segregated compounding area, not near garbage can, sink, window, door.	*N/A*

Immediate use

Compounding does not take place in ISO Class 5 PEC.	*N/A*
Low risk, non-hazardous CSP.	*N/A*
Compounding procedure is continuous not exceeding 1 hour & administration begins no later than 1 hour from start of compounding, if not CSP is discarded.	*N/A*
During compounding, aseptic technique is followed and if not immediately administered the CSP is under continuous supervision to minimize contact with non-sterile items.	*N/A*
CSP is immediately and completely administered by compounder or witnessed by compounder, if not must be labeled with patient identifier, names and amounts of all components, name or initials of compounder, and exact 1-hour BUD and time.	*N/A*

CAI not Located in ISO Class 7

Documentation from CAI manufacturer the ISO Class 5 environment is maintained under dynamic conditions when not located in an ISO Class 7 environment.	*N/A*
Documentation from CAI manufacturer of recovery time to achieve ISO Class 5 air quality when turn off and on and when transferring material from ante chamber to main chamber before and during compounding.	*N/A*
CAI located in low traffic area.	*N/A*
Documentation from CAI manufacturer compounder Is exempt from garbing.	*N/A*
CAI Pressures documented each shift, minimum of daily. Main chamber at least positive 0.02 inch water column to ante chamber and ante chamber at least positive 0.02 inch water column to general pharmacy.	*N/A*
Daily/shift documented cleaning of CAI, in the following order: top, back, sides, racks/poles, inside front, gauntlets, items on deck, deck, and ante chamber in same order.	*N/A*
Personnel appropriately garbed while cleaning CAI.	*N/A*
All items cleaned and disinfected before placing in ante chamber of CAI.	*N/A*
Temperature is recorded daily.	*N/A*
Controlled storage areas for room temperature is 68 to 77 F or 20 to 25 C.	*N/A*
Controlled storage area for cold temperature is 36 to 46 F or 2 to 8 C.	*N/A*
Controlled storage area for freezer temperature is -13 to 14 F or -25 to -10 C.	*N/A*

High Risk

Active Pharmaceutical Ingredient (API): Certificate of Analysis on file.	*Compliant*

Active Pharmaceutical Ingredient (API): Use USP or NF product and if not, safety and purity established.	*Not inspected*
Active Pharmaceutical Ingredient (API): Label bears batch or lot number.	*Compliant*
Active Pharmaceutical Ingredient (API): Label bears expiration date, if not, an expiration date of no more than 1 year from date of receiving is assigned.	*Compliant*
Pharmacy marks API with date received.	*Compliant*
If pharmacy puts API in smaller container for ease of use, container bears name of API.	*Not inspected*
If pharmacy puts API in smaller container for ease of use, container bears date API was received.	*Not inspected*
If pharmacy puts API in smaller container for ease of use, container bears date API was transferred.	*Not inspected*
If pharmacy puts API in smaller container for ease of use, container bears batch or lot number of API.	*Not inspected*
If pharmacy puts API in smaller container for ease of use, container bears expiration date from manufacturer or pharmacy assigned expiration date of no more than 1 year from date of receiving.	*Not inspected*
APIs stored in tightly closed containers under temperature, humidity and lighting conditions per official monograph or suppliers.	*Compliant*
Pre-sterilization procedures for high risk CSP, weighing and mixing, shall be completed in no worse than ISO Class 8 environment.	*Compliant*
Appropriate sterilization methods used and documented.	*Compliant*
Terminal sterilization of non-sterile empty vials or stoppers/closures used and documented.	*Compliant*
Pre-filter with 1.2 micron to remove large particles, if needed.	*Not inspected*
Filtration performed in ISO Class 5 environment.	*Compliant*
Documentation 0.2/ 0.22 micron sterile, non-pyrogenic microporous membrane filter is chemically/physically compatible with CSP.	*Compliant*
Filtration is completed rapidly without filter replacement.	*Not inspected*
Filter integrity testing is performed and documented for each filter used with each batch sterilized by filtration.	*Compliant*
Written documentation of description of steam sterilization includes conditions and duration for specific CSP.	*Compliant*

High Risk *(continued)*

Prior to sterilizing, plastic, glass and metal devices are tightly wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent post-sterilization microbial penetration.	*Compliant*
Autoclave allowed to reach 121 C before starting sterilization process.	*Compliant*
Usual expose to 121 C at 15 psi for 20 – 60 minutes. Maintains log of temperature and exposure time for each steam sterilized CSP.	*Compliant*
Ensures steam contacts all ingredients and surfaces to be sterilized.	*Compliant*
Autoclave was mapped.	*Compliant*
Effectiveness of steam sterilization is verified each time using biological indicators (BI) and temperature-sensing devices.	*Compliant*
For dry heat sterilization, heat filtered air is evenly distributed throughout the chamber with a blower.	*Compliant*
Dry heat oven is equipped with system for controlling temperature and exposure period and has been mapped.	*Compliant*
Sufficient space is left between materials to allow circulation of hot air.	*Not inspected*
Written documentation of description of dry heat includes conditions and duration for specific CSP.	*Compliant*
Effectiveness of dry heat sterilization is verified each time using biological indicators (BI) and temperature-sensing devices.	*Compliant*
For depyrogenation by heat used to render glassware, containers, vials free from pyrogens and viable microbes. Cover tightly with aluminum foil, bake at 250 C for 30 minutes, use immediately or if stored must be ISO Class 7 environment.	*Compliant*
For depyrogenation by heat written documentation of description of cycle and duration for specific load items.	*Compliant*
For depyrogenation by heat effectiveness of cycle is verified using Endotoxin Challenge Vials (ECVs) with bacterial endotoxin testing performed on ECVs to verify the cycle is capable of achieving a 3 log reduction in endotoxins.	*Compliant*
If depyrogenated glassware, containers, and/or vials are not used immediately, must be kept tightly covered with aluminum foil and stored in an ISO 7 environment.	*Compliant*
Other methods of sterilization are used with documented procedures and validation performed.	*Not inspected*

Extending BUD and Sterility Testing

Sterility testing for both bacteria and fungus performed each time BUD is extended beyond USP guidelines.	*Compliant*
Sterility testing performed on high risk CSP prepared in groups of more than 25 identical containers.	*Compliant*
Sterility testing performed on high risk CSP exposed longer than 12 hours at 2-8C (36-46F) or longer than 6 hours at warmer than 8C (46F) before sterilization.	*Not inspected*
Sterility testing is done using membrane filtration (preferred method) or direct inoculation per USP <71>.	*Compliant*
Appropriate number of CSPs tested for sterility per UPS <71> for parenterals: less than 100 units, test 10% or 4 units, whichever is greater; for 100-500 units, test 10 units; and for greater than 500 units, test 2% or 20 units, whichever is less.	*Compliant*
Appropriate number of CSPs tested for sterility per UPS <71> for large volume parenterals: 2% or 10 containers, whichever is less.	*Compliant*
Appropriate number of CSPs tested for sterility per UPS <71> for non-parenterals (eye drops, inhalations): less than 200 units, test 5% or 2 units, whichever is greater; for 200 or more units, test 10 units; and if packaged as unit dose, use parenteral testing numbers.	*Compliant*
Bacterial endotoxin testing performed on high risk CSP if prepared in groups of more than 25 identical containers.	*Compliant*
Bacterial endotoxin testing performed on high risk CSP if exposed longer than 12 hours at 2-8C (36-46F) or longer than 6 hours at warmer than 8C (46F) before sterilization.	*Not inspected*
CSP quarantined until results of sterility and endotoxin tests received or if dispensed before receiving results, written procedure requiring daily observation of incubating CSPs and immediate recall when evidence of growth. Patient and prescriber notified of potentially contaminated CSP and potential risk.	*Compliant*
Positive sterility test results promptly investigated including aseptic technique, environmental control, etc. to identify source of contamination and correct the issue.	*N/A*
Stability data documented to support extended BUD, either from literature or testing.	*Not inspected*
Method suitability test performed on CSP for stability data derived from testing.	*Not inspected*
If potency testing is performed, strength must be within 10% of stated potency.	*Compliant*

Transporting CSP Outside Facility

P&P for packing containers specifying which to use.	*Compliant*
P&P for insulating and stuffing materials specifying which to use.	*Compliant*
Written instructions to patients how to safely open containers of CSP.	*Compliant*

Transporting CSP Outside Facility *(continued)*

Ascertain temperature of CSP during transit.	*Compliant*
Specific handling and exposure instructions on the exteriors of containers packed with CSPs.	*Compliant*
Periodic review of delivery performance of couriers to ascertain CSPs are being efficiently and properly transported.	*Compliant*
Provide CSP labeling that includes clearly readable BUDs, storage instructions, and disposal information for out of date units.	*Compliant*
Ascertain each patient is able to store CSP properly, including use of properly functioning refrigerator or freezer if needed.	*Compliant*

Board Approved Waivers

Board has approved a waiver for non-hazardous sterile compounding.	*N/A*
Board has approved a waiver for hazardous sterile compounding.	*N/A*

Inspector's Signature

I have completed this inspection in accordance with the statutes and administrative codes.

Inspector: *Jessica Williams*

Pharmacist's Signature

I have read and understand the statutes and administrative codes. I acknowledge that the items noted in this report have been discussed with me. I understand that if I disagree with any of the deficiencies cited, that I have the right to refute them on this report or and other form that I choose to send to the department.

Pharmacist: *Nick Kirkpatrick*

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Resident Pharmacy

EFFECTIVE DATE: 12/21/2021

NUMBER: P08205

EXPIRATION DATE: 06/30/2024

PIC: NICHOLAS R. KIRKPATRICK

Issued to:
WICKLIFFE LLC
dba WICKLIFFE VETERINARY PHARMACY

4340 GEORGETOWN ROAD
LEXINGTON, KY 40511

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address. and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

brvlicensing@bluerabbit.vet

ANDY BESHEAR
GOVERNOR

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort, Kentucky 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

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EXECUTIVE DIRECTOR
CHRISTOPHER P. HARLOW, PHARM.D.

April 12, 2024

STATE OF KENTUCKY

COUNTY OF FRANKLIN

Re: **Wickliffe Veterinary Pharmacy**
4340 Georgetown Road
Lexington, KY 40511

No.: **P08205**

I, Christopher P. Harlow, Executive Director of the Kentucky Board of Pharmacy, do hereby certify that I am an official custodian of the records of said Board and pursuant to a request, I have searched Board records and certify that as of this date **Wickliffe Veterinary Pharmacy** does not have any actions on file with the Kentucky Board of Pharmacy.

Wickliffe Veterinary Pharmacy currently holds an Active Kentucky Pharmacy permit, number **P08205**, first issued on December 21st, 2021, and will expire on June 30th, 2024.

Witness my official hand and seal of the Board on April 12, 2024.

Christopher P. Harlow, Pharm.D.
Executive Director
Kentucky Board of Pharmacy

TEAM KENTUCKY
An Equal Opportunity Employer M/F/D

Corporate Information
Wedgewood Pharmacy LLC
Wedgewood Connect LLC

Officers:

President:	Joseph Costa
CFO & Treasurer	Maria Kraus
Secretary	Marcy Bliss

Parent Companies:

Wedgewood Holdings Inc. (100% owner of Wedgewood Pharmacy LLC)
Specialty Pharma III Inc. (100% owner of Wedgewood Holdco Inc)
Specialty Pharma II Inc. (100% owner of Specialty Pharma III Inc.)
Specialty Pharma I Inc. (100% owner of Specialty Pharma II Inc.)
Specialty Pharma Holdings LP (100% owner of Specialty Pharma I Inc.)

Address:

405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Officers:

President & COO:	Joseph Costa
CFO:	Maria Kraus
CEO & Sec.:	Marcy Bliss

Directors:

Marcy Bliss
Sofia Gerard
Dennis Maloney
Kevin Vasquez
David Kamenetzky
Peter Berweger

Shareholders:

There are no individual shareholders in Wedgewood Connect/Village Pharmacy as both entities are member managed limited liability companies.

All shares in Wedgewood Holdings Inc. are held by Specialty Pharma III Inc.

Marcy Bliss, Maria Kraus and Joseph Costa have served as officers at the following pharmacy locations:

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
7631 E. Indian School Road, Suite 105
Scottsdale, AZ 85251

ZooPharm LLC (now closed)
3131 Grand Ave., Unit C, Laramie, WY 82070

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Wickliffe LLC d/b/a Wickliffe Veterinary Pharmacy

Pharmacy/Wholesaler License # (if applicable): P08205 (KY); PH02575 (NV)

Physical Address: 4340 Georgetown Road

City: Lexington State: Kentucky Zip: 40511

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (859) 389-7470 Website: www.wicklifferx.com

Licensing Company Email: brvlicensing@bluerabbit.vet

Section 2: Personal Information

First: Nicholas Middle: Last: Kirkpatrick

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Georgetown Road

City: Lexington State: Kentucky Zip: 40511

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
East Tennessee State University Bill Gatton College of Pharmacy			08/12 - 05/16	
Address		**City**	**State**	**Zip**
PO Box 70414		Johnson City	TN	37614
Diploma/Degree obtained, if any				
PharmD				
School Name			**From - To (MM/YY – MM/YY)**	
University of Kentucky			08/09 - 05/12	
Address		**City**	**State**	**Zip**
410 Administration Drive		Lexington	KY	40506
Diploma/Degree obtained, if any				
Bachelor of Science - Human Nutrition				
School Name			**From - To (MM/YY – MM/YY)**	
West Kentucky Community and Technical College			05/09 - 08/09	
Address		**City**	**State**	**Zip**
4810 Alben Barkley Drive		Paducah	KY	42001
Diploma/Degree obtained, if any				
Associate of Science				
School Name			**From - To (MM/YY – MM/YY)**	
Heath High School			08/04 - 05/07	
Address		**City**	**State**	**Zip**
4330 Metropolis Lake Rd		West Paducah	KY	42086
Diploma/Degree obtained, if any				
High School Graduate				
School Name			**From - To (MM/YY – MM/YY**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/16 - Present	[redacted] Horsemint Trail	Lexington	KY	40509
08/12 - 06/16	[redacted] Judd Lane	Johnson City	TN	37604
08/10 - 08/12	Simpson Avenue	Lexington	KY	40504

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Wickliffe LLC d/b/a Wickliffe Veterinary Pharmacy			05/20 - Present
Business Address	**City**	**State**	**Zip**
4340 Georgetown Road	Lexington	KY	40511
Phone	**Title**	**Number of Employed Hours**	
(859) 389-7470	Pharmacist-In-Charge	40-50 hours/week	

Description of Duties

- Ensure proper storage, handling, and preparation of medications in the pharmacy.
- Ensure appropriate dispensing of medications to patients.

Business Name			From - To (MM/YY – MM/YY)
Tailor Made Compounding			12/16 - 05/20
Business Address	**City**	**State**	**Zip**
200 Moore Drive	Nicholasville	KY	40356
Phone	**Title**	**Number of Employed Hours**	
859-887-0013	Staff Pharmacist	40-50 hours/week	

Description of Duties

- Oversaw sterile pharmacy operations and managed inventory and pharmacy technicians.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/28/2020	07/30/2020	KS	Topeka	Shawnee
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
20-224		Kansas State Board of Pharmacy		
Reason/Charge				
For failing to timely report to the Kansas Board a change of his position as pharmacist-in-charge of his prior employer.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Kansas State Board of Pharmacy		Kansas Board of Pharmacy Order		
Name of Business/Industry/Entity				
Nicholas Kirkpatrick				

Provide explanation below:

Mr. Kirkpatrick was disciplined by the Kansas State Board of Pharmacy (case no. 20-224) on July 30, 2020, for failing to timely report to the Kansas Board a change of his position as pharmacist-in-charge of his prior employer. Mr. Kirkpatrick was disciplined and fined $120. His Kansas license is currently active, in good standing, and unencumbered. A copy of the order is enclosed herein.

Original Signature (electronic, copies or stamps not accepted)

6/2/2023
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
07/30/2020	02/10/2021	AL	Birmingham	Shelby
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
20-L-0104		Alabama State Board of Pharmacy		
Reason/Charge				
Sister state discipline based on Kansas Board of Pharmacy's Order				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Alabama State Board of Pharmacy		Alabama Board of Pharmacy Order		
Name of Business/Industry/Entity				
Nicholas Kirkpatrick				

Provide explanation below:

The Kansas Board's discipline led to a sister state discipline by the Alabama Board (case no. 20-L-0104) on February 10, 2021. Mr. Kirkpatrick was disciplined and paid an administrative fee of $500. His Alabama license is currently active, in good standing, and unencumbered. A copy of the order is enclosed herein.

Original Signature (electronic, copies or stamps not accepted)

6/2/2023
Date

I, Nicholas Kirkpatrick, **certify that as the designated representative for**

Wickliffe LLC d/b/a Wickliffe Veterinary Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. NK I am at least 21 years of age;
3. NK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. NK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. NK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. NK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. NK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Nicholas Kirkpatrick

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/2/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nicholas Kirkpatrick

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/2/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Fayette

I, Nicholas Kirkpatrick, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/2/2023

Date

Subscribed and Sworn to before me this 2 day of June 2023

Notary Public Signature

LINDA C RAMSEY
Notary Public-State at Large
KENTUCKY - Notary ID # KYNP26196
My Commission Expires 03-26-2025

(Seal)

DocuSign Envelope ID: 1D04AAAF-ABC6-4B1E-B2A8-50EA7158ACEB

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
NICHOLAS RICHARD KIRKPATRICK	)	**BOARD OF PHARMACY**
	)	
License No. 20021	)	**CASE NO: 20-L-0104**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Nicholas Richard Kirkpatrick (hereinafter referred to as "Kirkpatrick") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement, which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds Kirkpatrick violated the provision of law set out in Count Two of the Statement. Counts One and Three of the Statement shall be dismissed with prejudice.

2. Kirkpatrick shall pay an administrative fine in the amount of Five Hundred Dollars ($500.00) within thirty (30) days of the effective date of this Consent Order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Kirkpatrick attempt to discharge the same.

3. Kirkpatrick expressly waives his rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform

Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against him and any judicial review. Kirkpatrick further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

5. By execution of this Consent Order, Kirkpatrick hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

6. Kirkpatrick acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules of the Alabama State Board of Pharmacy or the pharmacy law or Rules of the Board of Pharmacy of another state or any other applicable laws, upon proof and hearing thereof, may result in further disciplinary sanctions against his license, including, but not limited to revocation.

7. Kirkpatrick acknowledges and agrees that he has read this Consent Order and that he fully understands the terms, conditions and contents of the same. Kirkpatrick acknowledges and agrees that he voluntarily and of his own free will accepts the terms and conditions set out in this Consent Order and had the opportunity to seek legal counsel prior to the execution of this Consent Order.

DocuSign Envelope ID: 1D04AAAF-ABC6-4B1E-B2A8-50EA7158ACEB

DONE this the 5th day of February, 2021.

Nicholas Richard Kirkpatrick

DONE this the 10th day of February, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Brenda Denson, Pharm.D., President

James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

DocuSign Envelope ID: 1D04AAAF-ABC6-4B1E-B2A8-50EA7158ACEB

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
NICHOLAS RICHARD KIRKPATRICK	)	**BOARD OF PHARMACY**
	)	
License No. 20021	)	**CASE NO: 20-L-0104**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Nicholas Richard Kirkpatrick
3700 Horsemint Trail
Lexington, Kentucky 40509

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on February 16, 2021 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why your license to practice pharmacy in this State should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that you have been guilty of the following, to wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the Summary Order entered by the Kansas Board of Pharmacy on July 30, 2020 attached hereto as Exhibit "A" and/or your failure to timely notify the Kansas Board of your resignation as the PIC for Tailor Made Compounding, i.e. you resigned on May 28, 2020 and did not notify the Kansas Board until June 26, 2020 as more fully set out in the Order referenced above.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

Further, pursuant to the provisions of Code of Alabama (1975), § 20-2-53 and § 41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), § 20-2-1, et. seq., issued pursuant to Code of Alabama (1975), § 20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT THREE

Violating Code of Alabama (1975), § 20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), § 34-23-1 et seq., said violation being based upon the allegations contained in any or all of the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 19th day of October, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW1055880	05-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-27-2021

WICKLIFFE, LLC DBA WICKLIFFE VETERINARY PHARMACY
4340 GEORGETOWN RD
LEXINGTON, KY 405119115

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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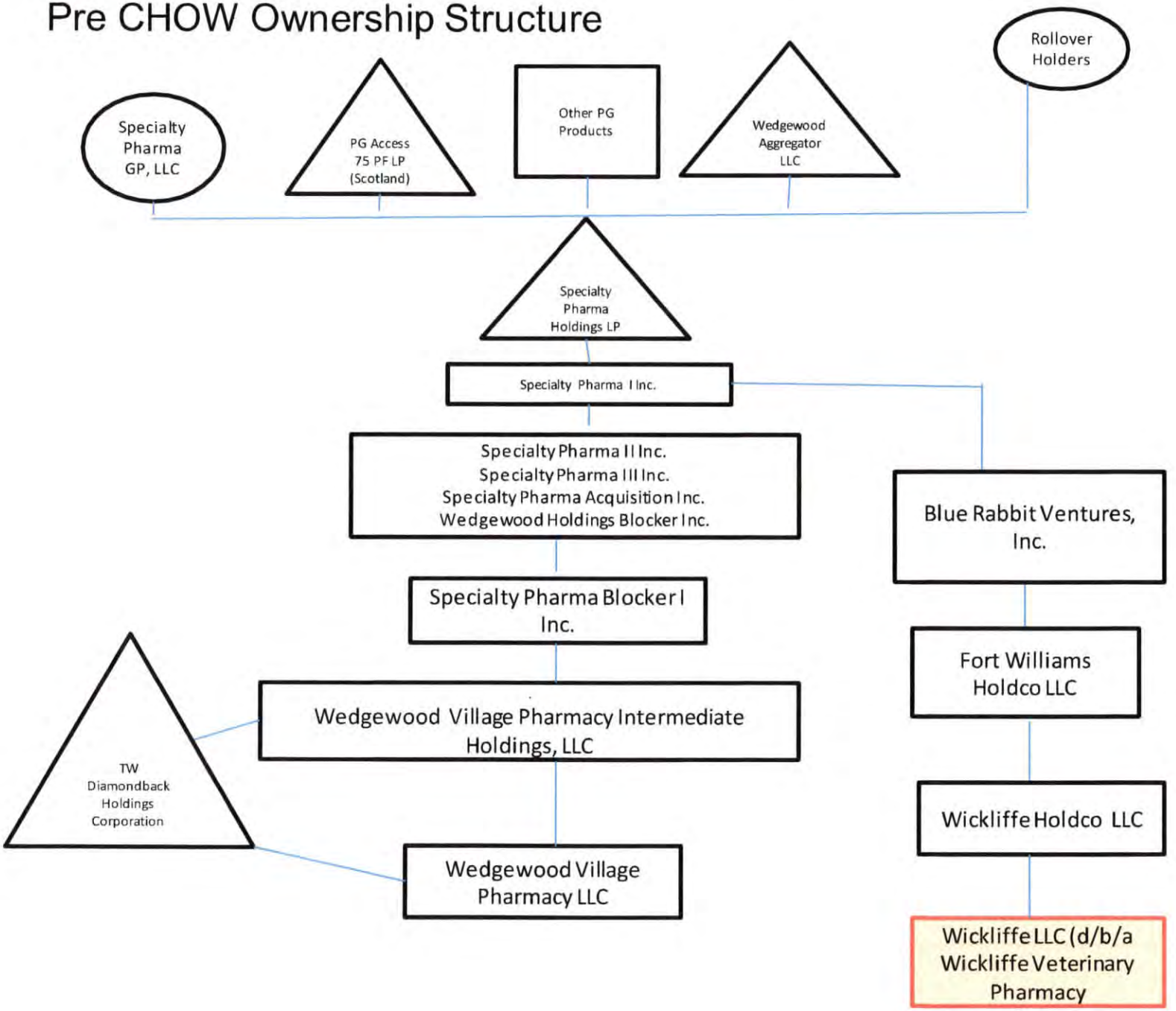
WICKLIFFE, LLC DBA WICKLIFFE VETERINARY PHARMACY
4340 GEORGETOWN RD
LEXINGTON, KY 405119115

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

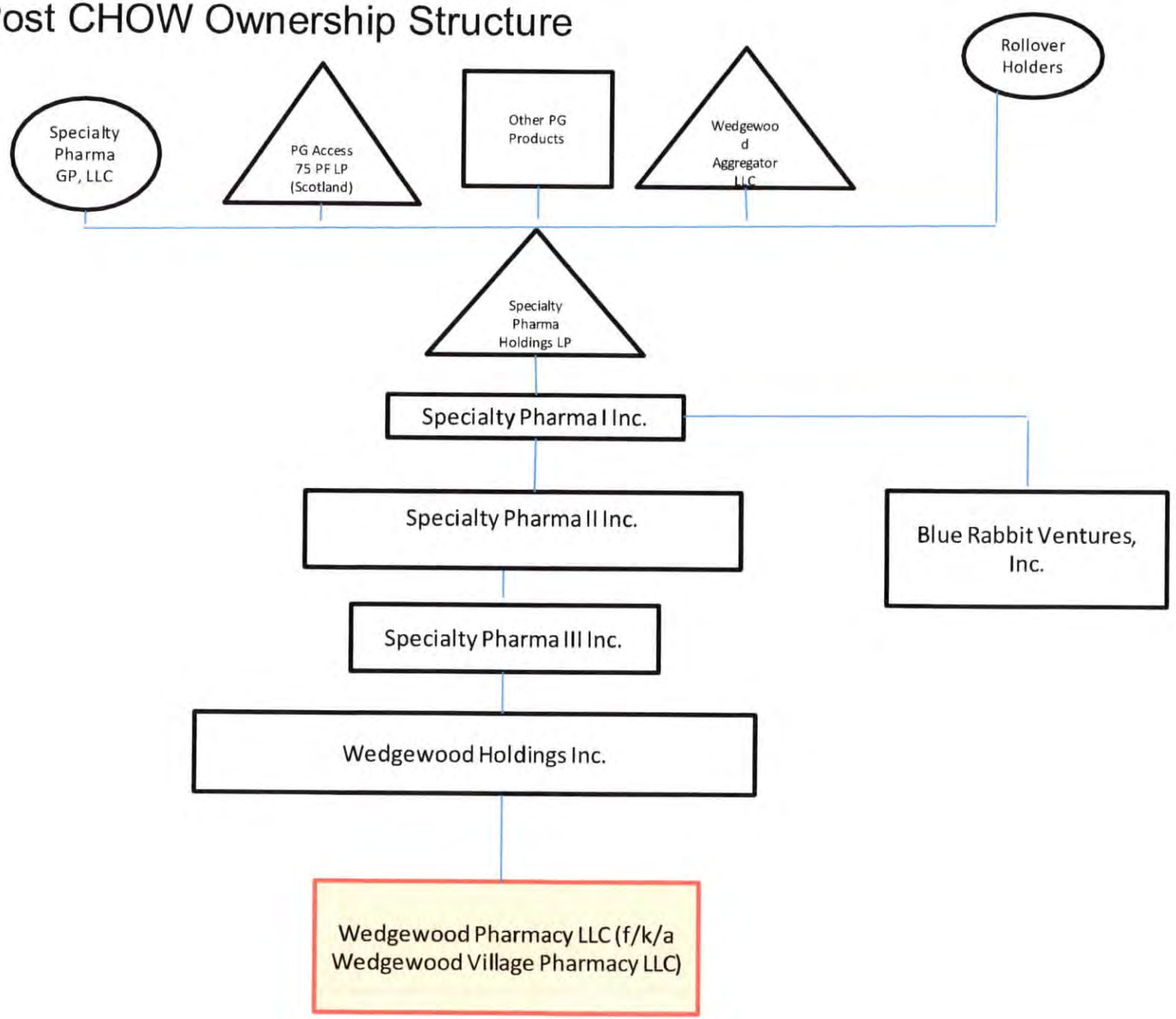
THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Pre CHOW Ownership Structure



Post CHOW Ownership Structure



wedgewood PHARMACY

April 15, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

RE: Change of Ownership Wickliffe Veterinary Pharmacy
License Number: PH02575

To Whom It May Concern

Please be advised we have not included a new Designated Representative Application as our Nevada licensed Pharmacist-in-Charge/Designated Person (PIC/DP) has not changed since our last application. Additionally, Nicholas Kirkpatrick, our PIC/DP, completed this form within the last year and the BOP has his information on file.

Should you have any questions or require additional information, please do not hesitate to contact me at (559)-361-2342 or rachel.taggs@precisionpharmacy.com.

Sincerely,

Rachel Taggs
Sr. Compliance Specialist

Section 3: History of Company

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?

Wedgewood Pharmacy LLC

The list includes prior matters that have previously been reported to the Board in an effort to provide full transparency with the application.

Please note that Wedgewood Pharmacy has operated in two locations so the matters are being reported specific to the applicable facility.

Discipline and Closed Matters for Wedgewood Village Pharmacy LLC, Swedesboro, NJ Location

03/19/2015 – MN/MI/AL Consent Orders

On March 19, 2015, Wedgewood entered into a consent order with the Minnesota Board of Pharmacy (*"Minnesota Consent Order"*). Wedgewood subsequently entered into consent orders with the Michigan Department of Licensing and Regulatory Affairs (*"Michigan LARA"*) and the Alabama Board of Pharmacy ("Alabama BOP") to resolve "sister state" actions that arose out of the Minnesota Consent Order.

The basis for the Minnesota Consent Order are as follows:
Acting on a reasonable and good-faith interpretation of Minnesota law, Wedgewood from its NJ location, dispensed compounds to licensed veterinarians in Minnesota, pursuant to a veterinarian's order for office use. The Minnesota Board asserted that Wedgewood needed a wholesale license to engage in this activity. For the purposes of settlement only, Wedgewood entered into the Minnesota Consent Order whereby it agreed to a $10,000 civil penalty but admitted no wrongdoing.
Wedgewood subsequently entered into a consent order with the Michigan LARA to resolve a "sister state" action brought by Michigan based on the Minnesota Consent Order. Wedgewood entered into a similar consent order with the Alabama BOP to resolve a sister state action brought by Alabama based on the Minnesota Consent Order. There was no finding in the Michigan or the Alabama Consent Order that Wedgewood violated any provisions of Michigan or Alabama state law outside of these states' prohibitions on sister state actions.

10/22/2015 – New Jersey Consent Agreement

On October 22, 2015, Wedgewood Village Pharmacy, Inc., entered into a Consent Agreement with the New Jersey Board of Pharmacy resolving a dispute between the parties on the application of "beyond use dating" regulations for sterile compounds.

This is the same order that is referenced on the Swedesboro, NJ facility's home license however, per the terms of the Agreement, it is not to be construed as discipline and any reimbursement paid to the Board is not considered a fine or other sanction.

10/13/2017 – California Citation & Fine

Issued as a result of an investigation by the CA BOP into an unlicensed individual who fraudulently set up an account with Wedgewood as a veterinarian using valid prescriber license information he acquired unlawfully. An administrative citation was issued and Wedgewood paid a nominal fine.

07/20/2018 - DEA Memorandum of Agreement

While Wedgewood does not consider there to be a restriction on its handling of CDS or disciplinary action, however, out of an abundance of caution, Wedgewood is disclosing the following:

As a condition of issuing Wedgewood located in Swedesboro, New Jersey a DEA manufacturer registration, Wedgewood and the DEA entered into a Memorandum of Agreement ("MOA") for a period of five years (until July 20, 2023) during which Wedgewood agreed not to use the DEA manufacturer license to manufacture or distribute controlled substances for human use. Wedgewood obtained a DEA manufacturer registration for the sole purposes of providing controlled substance compounds solely for veterinarians to use for office use.

12/5/2018 – California Citation

The California Board of Pharmacy issued a non-disciplinary, Administrative Citation with no penalty or fine based on a California Board inspector's interpretation of California regulations. In the Inspector's opinion, providing a 15ml ophthalmic container to a veterinarian for office use exceeded the "reasonable quantity" limitation for office use compounds.

Wedgewood discontinued sales of all 15ml ophthalmic container for office use to California veterinarians. The Board issued a Close Out letter on March 1, 2019. No penalty or fine was assessed.

6/17/2021 – California Citation & Fine

Received notification of a non-disciplinary, Administrative Citation which was finalized on 07/29/2021. A fine was paid as part of the final citation. The basis for the citation was that Wedgewood did not have the necessary data to support the "beyond use dates" Wedgewood used.

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

On February 21, 2024, the California Board of Pharmacy (the "Board") approved a Stipulated Settlement and Disciplinary Order for Public Reproval entered into with Wedgewood Village Pharmacy LLC relating to claims made by the Board regarding assignment of unsupported beyond use dates and other matters. The Order became effective on March 22, 2024 and Wedgewood agreed to pay the Board $11,054.75 as reimbursement of its costs in connection with this matter.

Discipline and Closed Matters for Wickliffe Veterinary Pharmacy Lexington Kentucky

01/10/2024 – Alaska Imposition of Civil Fine

On August 8, 2023, Wickliffe received a complaint from the Alaska Board of Pharmacy concerning the omission of past discipline of the pharmacist in charge for the facility. A clerical error was made on the initial application and the information was not included. However, the information was provided on an updated application. The matter has been resolved through the consent order and a nominal fine will be paid upon Board approval of the order.

Rachel Taggs

Sr. Compliance Specialist
Wedgewood Pharmacy

MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

2829 University Ave. SE., #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (651) 201-2837
MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:
Metro and Non-Metro; 800-627-3529
E-Mail Address: Pharmacy.Board@state.mn.us
Web Site: www.pharmacy.state.mn.us

MAR 19 2015

PERSONAL & CONFIDENTIAL

March 16, 2015

Gregory P. Bulinski
Attorney
Bassford Remele
33 South Sixth Street, Suite 3600
Minneapolis, MN 55402-3707

Re: In the Matter of Wedgewood Pharmacy
License No. 262173

Dear Mr. Bulinski,

Enclosed and served upon you in the above-referenced matter is the fully executed Stipulation and Consent issued by the Board of Pharmacy.

Sincerely,

Cody Wiberg

Cody Wiberg, Pharm D, MS, RPh
Executive Director

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remele and Rachael G. Pontiltes, Esq., of Duane Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

MARCY HLISS, PRESIDENT
Wedgewood

Dated: 1/13/15

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

IN THE MATTER OF:	)	
	)	BEFORE THE ALABAMA STATE
WEDGEWOOD VILLAGE PHARMACY, LLC	)	BOARD OF PHARMACY
	)	
Non-Resident Pharmacy Permit Number: 112625	)	CASE NO: 16-L-0066

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Wedgewood Village Pharmacy, LLC ("Wedgewood") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Wedgewood through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Wedgewood has violated the "sister-state" provisions of Alabama law as set out in the Statement of Charges.

2. Wedgewood shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Wedgewood expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975),

§34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Wedgewood further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Wedgewood hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Wedgewood acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Wedgewood's permit, including, but not limited to revocation.

6. Wedgewood acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wedgewood acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 6th of June, 2017.

WEDGEWOOD VILLAGE PHARMACY, LLC

BY: [signature]

ITS: President & CEO

[signature]

Jennifer Clark, attorney for Wedgewood Village Pharmacy, LLC

DONE this the ____ of 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

Buddy Bunch

By: _____

Buddy Bunch, R.Ph., President

By: _____

James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 560
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF: WEDGEWOOD VILLAGE PHARMACY, LLC Non-Resident Pharmacy Permit Number: 112625	BEFORE THE ALABAMA STATE BOARD OF PHARMACY CASE NO: 16-L-0086

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Wedgewood Village Pharmacy, LLC
405 Heron Drive
Suite 200
Swedesboro, New Jersey 08085

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on _____, 2016 at _____m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Wedgewood Village Pharmacy, LLC (Wedgewood) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Wedgewood has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Stipulation and Consent Order by the Minnesota Board of Pharmacy on January 4,

2015 attached hereto as Exhibit "A" and/or the Facts set out therein that you shipped drugs to licensed veterinarians in Minnesota without patient specific prescriptions nor the required license to do so.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon the Consent Order entered by the State of Michigan Board of Pharmacy on April 13, 2016 as a result of the filing of an Administrative Complaint, these documents being attached hereto as Exhibits "B" and "C".

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FOUR

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of

the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the _____ day of _____, 2016.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT "A"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goelz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullock, Esq., of Hazeltine Rensle and Rachael G. Pentikes, Esq., of Dunn Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

11. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 3. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

MARCY ELSER, PRESIDENT
Wedgewood

Dated: 1/13/15

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT "B"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remele and Rachael C. Pontikes, Esq., of Dunn Morris.

EXHIBIT A page 1 of 7

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2018, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

EXHIBIT A page 2 of 7

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

EXHIBIT A page 3 of 7

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

EXHIBIT A PAGE 4 of 7

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 131.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

EXHIBIT A page 5 of 7

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

EXHIBIT A page 6 of 7

CONSENT:

MARGY KLISS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT A page 7 of 7

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Fitzgerald (P-65844)
Assistant Attorney General
Attorney for Complainant
Dated: 9-1-2016

AGREED TO BY:

Alison Leidy, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 8/31/16

Alan T. Hegarty (P-34550)
Attorney for Respondents
Dated: 8/31/16

EXHIBIT "C"

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the matter of

WEDGEWOOD VILLAGE PHARMACY INC.
License Number: 53-01-008041 File Number: 53-15-137238

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs (Complainant) by Kim Goedeke, Acting Director, Bureau of Health Care Services, files this Complaint against Wedgewood Village Pharmacy Inc. (Respondent Pharmacy) as follows:

1. The Michigan Board of Pharmacy (Board) is an administrative agency established by the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq. Pursuant to section 17768 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent Pharmacy is licensed to practice as a pharmacy in the state of Michigan and has an address of record with Complainant of Swedesboro, New Jersey.

3. On January 21, 2015, the Minnesota Board of Pharmacy (Minnesota Board) executed a Stipulation and Consent Order which ordered Respondent Pharmacy

to pay a $10,000.00 civil penalty. The action was based on Respondent Pharmacy not being licensed as a drug wholesaler by the Minnesota Board and shipping drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. A copy of the Stipulation and Consent Order, marked Exhibit A, is attached and incorporated

COUNT I

The action by the Minnesota Board, as set forth above evidence a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty and constitutes a violation of section 17768(2)(d) of the Public Health Code, supra.

Complainant requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq.

Pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Kim Gaedeke, Acting Director, Bureau of Health Care Services, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

Pursuant to section 16231(9) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

DATED: 07/24/2015

Kim Gaedeke, Acting Director
Bureau of Health Care Services

Attachment

This is the final page of an Administrative Complaint in the matter of Wedgewood Village Pharmacy Inc., File Number 53-16-137238, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

DWC

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

Wedgewood Village Pharmacy, Inc.
License No. 53-01-008041

Complaint No. 53-15-137238

CONSENT ORDER AND STIPULATION

CONSENT ORDER

An administrative complaint was filed with the Disciplinary Subcommittee of the Board of Pharmacy on July 24, 2015, charging Wedgewood Village Pharmacy, Inc. (Respondent) with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended, MCL 333.1101 *et seq.*

The parties have stipulated that the Disciplinary Subcommittee may enter this consent order. The Disciplinary Subcommittee has reviewed the stipulation contained in this document and agrees that the public interest is best served by resolution of the outstanding complaint. Therefore, the Disciplinary Subcommittee finds that the allegations of fact contained in the complaint are true and that Respondent has violated section 17768(2)(d) of the Public Health Code.

Accordingly, for this violation, IT IS ORDERED:

Respondent is FINED $500.00 (Five Hundred Dollars) to be paid by check, money order or cashier's check made payable to the State of Michigan (with complaint number 53-15-137238 clearly indicated on the check or money order), and

shall be payable within 60 days of the effective date of this order. The timely payment of the fine shall be Respondent's responsibility. Respondent shall mail the fine to: Sanction Monitoring, Bureau of Professional Licensing, Enforcement Division – Compliance Section, Department of Licensing and Regulatory Affairs, P.O. Box 30189, Lansing, Michigan 48909.

This order shall be effective on the date signed by the Chairperson of the Disciplinary Subcommittee or the Disciplinary Subcommittee's authorized representative, as set forth below.

Signed on 4-13-16

MICHIGAN BOARD OF PHARMACY

By_____
Chairperson, Disciplinary Subcommittee

STIPULATION

The parties stipulate as follows:

1. Respondent does not contest the allegations of fact and law in the complaint. Respondent understands that, by pleading no contest, it does not admit the truth of the allegations but agrees that the Disciplinary Subcommittee may treat the allegations as true for resolution of the complaint and may enter an order treating the allegations as true.

2. Respondent understands and intends that, by signing this stipulation, it is waiving the right under the Public Health Code, rules promulgated under the Public Health Code, and the Administrative Procedures Act of 1969, 1969 PA 306,

as amended, MCL 24.201 *et seq.*, to require the Department to prove the charges set forth in the complaint by presentation of evidence and legal authority, and to present a defense to the charges before the Disciplinary Subcommittee or its authorized representative. Should the Disciplinary Subcommittee reject the proposed consent order, the parties reserve the right to proceed to hearing.

3. The Disciplinary Subcommittee may enter the above Consent Order, supported by Board conferee Patti Smeelink, R.Ph. Ms. Smeelink or an attorney from the Licensing and Regulation Division may discuss this matter with the Disciplinary Subcommittee in order to recommend acceptance of this resolution.

4. Conferee Smeelink and the parties considered the following factors in reaching this agreement:

A. Respondent has fully cooperated in this matter and since initially licensed in 2004, Respondent has never had any disciplinary action taken against its Michigan Pharmacy license prior to this incident.

B. Respondent timely reported the Minnesota Board of Pharmacy Stipulation and Consent Order to the Department.

C. The violation of MCL 333.17768(d)(2) as alleged in the Complaint is based solely on a "sister-state" action taken against Respondent's Pharmacy license by the Minnesota Board of Pharmacy that was based on Respondent's former practice in 2012 of dispensing compounded veterinary medications for office-use to licensed veterinarians in Minnesota, which according to the Minnesota Board of Pharmacy, required a wholesaler's license. However, this practice did not implicate Respondent's practice of pharmacy in the State of Michigan and Respondent has not been found to have violated the Michigan Public Health Code or Board of Pharmacy Administrative Rules, except as provided herein.

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Elizondo

Kelly K. Elizondo (P45584)
Assistant Attorney General
Attorney for Complainant
Dated: 5-1-2016

AGREED TO BY:

Alison Lynch, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 5/31/16

Alan T. Rozalski (P44550)
Attorney for Respondent
Dated: 5/31/2016

DMB:6772746.1

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street 5th Floor
P.O. Box 45029
Newark, New Jersey 07101

By: Megan Cordoma
Deputy Attorney General
Tel. No. (973) 648-4730

FILED
OCT 22 2015
BOARD OF PHARMACY

STATE BOARD OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF
THE REGISTRATION OF

WEDGEWOOD VILLAGE PHARMACY, INC.
Registration No.:28RS00316800

TO OPERATE A PHARMACY
IN THE STATE OF NEW JERSEY

Administrative Action

CONSENT ORDER

This matter was opened to the New Jersey Board of Pharmacy ("the Board") upon receipt of reports of inspection of the facility at Wedgewood Village Pharmacy, Inc. ("Wedgewood") which occurred on November 14 and 15, 2012. The reports document potential violations of the Board's regulations regarding sterile compounding. Wedgewood engages in high risk sterile compounding.

Among other things, the inspection reports highlighted routine professional practices suggesting that thousands of units of medication were dispensed with disregard for the following regulatory requirements:

- Use-by dates exceed 30 days after preparation in violation of N.J.A.C. 13:39-11.11.
- Failure to include date and time of preparation on prescription labels in violation of N.J.A.C. 13:39-11.10(a)(1).
- Failure to include the use-by date and use-by time on prescription labels as required by N.J.A.C. 13:39-11.10(a)(7).

No evidence of contamination was found. Wedgewood denies the allegations of violations and has been fully cooperative with the Board's investigation. There have been significant changes in management of Wedgewood since the time of the events in question. The pharmacy permit holder at the time of these events is now deceased and his wife now holds the permit. Wedgewood has agreed to replace the registered pharmacist-in-charge. Wedgewood represents that it is now in compliance with New Jersey statutes and regulations and with the USP guidelines. Wedgewood further represents that 100% of all sterile compounds are currently being tested for sterility and that all use-by dates are properly supported. Accordingly, the Board has determined that the monitoring requirements imposed herein are sufficient to protect the public health, safety and

welfare.

The parties, having agreed to resolution of this matter without formal proceedings, and Wedgewood, having agreed and given voluntary consent to the within order and waiving any right to a hearing, and the Board finding the within disposition adequately protective of the public health, safety, and welfare, and other good cause having been shown;

IT IS THEREFORE on this 22nd day of OCTOBER, 2015,

ORDERED AND AGREED that

1. Wedgewood shall contract with a third-party monitor (the "Monitor") pre-approved by the Board to review all compounding operations of the pharmacy. For the purposes of this Order, LDT Health Solutions, Inc. is an approved Monitor. Within 30 days of the entry of this Order, the Monitor shall furnish the Board directly with a report which demonstrates review of all processes and procedures, and attests to compliance with all Board regulations and USP standards. Wedgewood shall conduct environmental testing, pressure differential monitoring, and air and surface sampling for bacteria and fungi and make these test results available to the Monitor prior to the Monitor issuing its report and directly to the Board. Wedgewood shall continue to contract with the Monitor and the Monitor will submit reports directly to the Board on the first day of each month until the Monitor

reports directly to the Board that Wedgewood has complied with all recommendations made by the Monitor and is operating in full compliance with all Board regulations and USP standards. All costs associated with the monitoring outlined in this Order shall be the responsibility of, and paid directly by, Wedgewood.

2. Within 30 days of the entry of this order, Wedgewood shall appoint a new pharmacist-in-charge and shall ensure that a pharmacist with sterile compounding expertise (either the pharmacist-in-charge or another employee) directly supervises the daily sterile compounding operations to further ensure the quality and integrity of their products. "Directly supervise" for the purpose of this paragraph means ensure that all proper checks and balances are being performed during the compounding process; help identify and eliminate errors and mistakes; ensure training and testing of personnel testing is occurring; and generally help to ensure that proper aseptic technique is being used to help implement a Quality System and Environment to produce compounded sterile product.

3. Prior to hiring any pharmacist-in-charge or pharmacist to directly supervise daily sterile compounding operations, Wedgewood shall ensure that the individual is competent and that his/her license is not restricted in such a way as to preclude them from fulfilling their job responsibilities.

Wedgewood shall not hire an individual to be pharmacist-in-charge or to directly supervise the daily sterile compounding operations if Wedgewood is aware that the individual is subject to a pending Board investigation.

4. Wedgewood agrees to pay the Board the sum of $500,000.00 in two equal installments due on or before November 31, 2015 and December 31, 2015. This payment will reimburse the Board for attorney's fees and investigative costs and the remainder will be applied toward the Board's ongoing efforts to inspect, investigate and educate pharmacies involved in sterile compounding. Wedgewood and the Board acknowledge and agree that the payment described herein is not a fine, sanction, warning letter or penalty, or payment in lieu thereof. Payment shall be made by bank check, money order, wire transfer or credit card made payable to the New Jersey Board of Pharmacy.

5. This Consent Order shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability of the pharmacy.

NEW JERSEY STATE BOARD OF PHARMACY

By: Thomas F.X. Bender, Jr., RPh
Thomas F.X. Bender,
R.Ph., President

I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.

Ludmilla P Malmberg, Owner
and Permit Holder of
Wedgewood Village Pharmacy

Consent as to form and entry:

Angelo Cifaldi, Esq.
Attorney for
Wedgewood Village Pharmacy

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 13, 2017

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- November 12, 2017: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 27, 2017: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 12, 2017: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 12, 2017.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Ericka Busby
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7731

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 27, 2017 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 12, 2017 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 574-7924.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	$1,000.00

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | TOTAL AMOUNT OF FINE(S): $1,000.00

PAYMENT OF FINE(S) DUE BY: November 12, 2017

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	**A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board**	**$1,000.00**

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: November 12, 2017

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: WEDGEWOOD VILLAGE PHARMACY LLC NRP 1826 Respondent	Citation Case No : CI 2017 77042 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2017 77042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On October 13, 2017, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7017 0530 0001 1516 2087

I declare under penalty of perjury that the forgoing is true and correct.

Executed on October 13, 2017, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NRP 1826

Citation Number : CI 2017 77042

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☑ I contest the Citation and request an Office Conference.

Check One:

☑ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: Mary Ann Bliss

Signature: Mary Ann Bliss Dated: 10/26/17

Address of Service: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: (Business) (856) 832-1303 Residence: (609) 320-5050

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

UPS
1Z 54E 746 01
6470 45 82
Tracking #
10/26/17 3:12pm

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 23, 2017

Wedgewood Village Pharmacy
Attention: Alison Lynch
405 Heron Dr., Ste. 200
Swedesboro, NJ 08085

RE: Complaint Investigation CI 2016 72146

Dear Pharmacist-in-Charge:

The Board of Pharmacy has completed its investigation of Wedgewood Village Pharmacy.

As a regulatory agency, when conducting an investigation, the Board must adhere to violations prohibited in pharmacy law. Specifically, the information and documentation obtained during the course of an investigation must clearly demonstrate that a violation of pharmacy law occurred.

The Board's analysis of the information and documentation received did not identify sufficient evidence to determine that a violation of pharmacy law occurred. Accordingly, the Board is closing the matter and will be taking no action against the pharmacy or its licensees.

Although we are closing this matter, please be advised that it is your professional responsibility to assure compliance with all pharmacy laws.

We would like to thank you for your cooperation and assistance. If you should have any questions, please contact the Board at the above address or telephone number.

Sincerely,

VIRGINIA K. HEROLD
Executive Officer

By

Tina Rojas
Complaint Unit Analyst

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
NEW JERSEY DIVISION
CAMDEN RESIDENT OFFICE

IN THE MATTER OF:
Wedgewood Village Pharmacy, LLC
Wedgewood Animal Wellness, LLC
405 Heron Drive
Swedesboro, NJ 08085

DEA Application# W15007898E
DEA Application# W17088272E

MEMORANDUM OF AGREEMENT

On or about 2/5/2015, the Drug Enforcement Administration (DEA) received an application for controlled substance registration (DEA control number W15007898E) from Wedgewood Village Pharmacy, LLC 405 Heron Drive, Swedesboro, NJ 08085. On or about 8/18/2017, DEA received another application for controlled substance registration (DEA control number W17088272E) from Wedgewood Animal Wellness LLC, 405 Heron Drive, Swedesboro, NJ 08085.

This Memorandum of Agreement (MOA) between the DEA and Wedgewood Village Pharmacy LLC establishes terms and conditions under which the DEA will issue a registration to Wedgewood Village Pharmacy LLC as a Manufacturer to handle Schedules III through V controlled substances subject to the terms set forth below in this Memorandum of Agreement. This MOA applies only to the manufacturing registration to be issued to Wedgewood Village Pharmacy LLC.

Wedgewood agrees to enter into this MOA with the DEA for a period of five (5) years from the date the MOA is signed and fully executed. The MOA shall be considered fully executed when all parties to the MOA have signed and dated the MOA.

Wedgewood agrees to not manufacture or distribute any controlled substances for human use under the DEA issued manufacturing registration.

Wedgewood agrees to contact DEA immediately if there is any change to their business practice of selling controlled substances for animal use only pursuant to their DEA issued manufacturing registration.

Wedgewood shall abide by and obey all federal, state, and local laws and requirements relating to controlled substances.

Wedgewood agrees to immediately notify DEA if there is any change of status in its State of New Jersey license and/or State Controlled Dangerous Substance license, including any actions filed against these licenses.

Wedgewood agrees to allow DEA to conduct onsite inspections, including inspections of its controlled substances records, without prior notice pursuant to a Notice of Inspection of Controlled Premises and without requiring DEA to obtain an Administrative Inspection Warrant, Search Warrant, or other means of entry

Wedgewood agrees that this MOA constitutes the entire agreement between Wedgewood and DEA, and may only be modified or amended by a subsequent document executed in the same manner by both parties in writing.

Wedgewood shall report any professional, civil, or criminal action concerning controlled substances that is pending or taken against the firm by any state, federal, or professional agency or governing body to DEA, Camden Resident Office.

Wedgewood shall maintain a complete and accurate record of all controlled substances manufactured or distributed pursuant to this manufacturing registration.

Wedgewood agrees by executing this MOA, it waives judicial review, and will not challenge or contest the validity of any terms or conditions of this agreement.

The parties further agree that should Wedgewood violate any terms or conditions of this agreement, such violation may constitute grounds for the revocation, or the revocation and immediate suspension, of Wedgewood's DEA manufacturing registration. Nothing in this MOA shall preclude Wedgewood from contesting any subsequent Order to Show Cause, or Order to Show Cause and Immediate Suspension, of its DEA manufacturing registration as permitted under the Controlled Substances Act and the Administrative Procedure Act. Nothing in this MOA shall be construed as a waiver on the part of DEA to utilize any violations, past or subsequent, as grounds for revocation of Wedgewood's DEA manufacturing registration, either by themselves or in conjunction with other grounds, in the event that future DEA administrative proceedings become necessary. Furthermore, DEA is not precluded from introducing this MOA at any subsequent DEA administrative proceeding.

DEA agrees to promptly approve Wedgewood's application for a manufacturing registration, control# W15007898E, upon the signing of this MOA by both parties.

The parties agree that Wedgewood's application, control# W17088272E is withdrawn effective the execution of this agreement.

The responsible Wedgewood official below acknowledges and states that s/he has read the foregoing and understands and agrees with the contents herein and that s/he has signed this MOA.

The parties enter into this MOA with the understanding that the Drug Enforcement Administration and Wedgewood Village Pharmacy LLC will abide by its contents in good faith.

Wedgewood Village Pharmacy, LLC — Date: 7/20/18

FOR THE DRUG ENFORCEMENT ADMINISTRATION

Nancy Coffey
Diversion Program Manager
New Jersey Division — Date

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2016 73882
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2016 73882	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7938

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT

Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2018 82132
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2018 82132	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7945

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT

Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2018 82132
NRP 1826

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2018 82132 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NRP 1826
CITATION AND FINE CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4678

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

Jennifer Sevilla

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2016 73882
NSC 100970

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2016 73882 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NSC 100970
CITATION AND FINE CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4685

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

Jennifer Sevilla

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 90874
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2020 90874

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, June 17, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9670

I declare under penalty of perjury that the forgoing is true and correct.

Executed on June 17, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2020 90874	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

CITATION ISSUED ON: June 17, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation and Fine, Order of Abatement ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation and indicates, within the Order of Abatement, information and/or material to be submitted to the Board.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- July 17, 2021: Unless the Citation is contested, Proof of Abatement and payment of fine(s) must be received by the Board, or as directed in Order of Abatement at the bottom of your citation.
- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), timely payment of any fine(s) and the submission of Proof of Abatement shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations title 16 section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2020 89042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, April 28, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Order of Abatement, Proof of Abatement, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9687

I declare under penalty of perjury that the forgoing is true and correct.

Executed on April 28, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

Citation Number	Name, License No
CI 2020 89042	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**	**$2,500.00**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

In addition to the issued citation, Wedgewood Village Pharmacy shall provide (1) payment in the amount of $2,500.00 and (2) justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued.

If Wedgewood Village Pharmacy fails to provide justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued, this shall constitute a ground for revocation or suspension of your license, permit, or registration.

CITATION ISSUED ON: June 17, 2021	TOTAL AMOUNT OF FINE(S): $2,500.00
PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: July 17, 2021	

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 29, 2021

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

This is in response to the administrative fine and proof of abatement provided to the board for the above referenced citation. The payment and documentation have been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Enforcement Manager, Susan Cappello at (916) 518-3008.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 21, 2024

CERTIFIED MAIL

Wedgewood Village Pharmacy
Attn: Marcy Ann Bliss, CEO
405 Heron Drive
Swedesboro, NJ 08085

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy LLC, dba Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

Dear Ms. Bliss:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to pages 5 – 6 of the document.

Effective at 5:00 p.m. on March 22, 2024, Nonresident Pharmacy Permit Nos. NRP 2526 & NRP 1826 and Nonresident Sterile Compounding Permit Nos. NSC 101673 & NSC 100970 issued to Wedgewood Village Pharmacy, shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Kristina T. Jarvis, DAG
Derek Shaffer, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
Wedgewood Village Pharmacy Attn: Marcy Ann Bliss, CEO 405 Heron Drive Swedesboro, NJ 08085	9589 0710 5270 0843 9755 17
Quinn Emanuel Urquhart & Sullivan, LLP Attn: Derek Shaffer, Esq. 1300 I St., NW., Ste. 900 Washington, D.C. 20005	9589 0710 5270 0843 9755 24

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 21, 2024, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 21, 2024, at Sacramento, California

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

WEDGEWOOD VILLAGE PHARMACY LLC; dba
WEDGEWOOD VILLAGE PHARMACY;
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 2526,
Nonresident Sterile Compounding Permit No. NSC 101673; and

WEDGEWOOD VILLAGE PHARMACY LLC;
WEDGEWOOD VILLAGE PHARMACY
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondents

Agency Case No. 7286

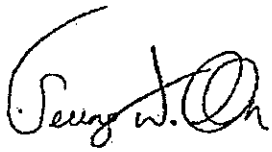
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 22, 2024.

It is so ORDERED on February 21, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC; 405 Heron Drive Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526, Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; ALISON LYNCH, PIC; 405 Heron Drive, Suite 200 Swedesboro, NJ 08085**	Case No. 7286 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970

Respondents.

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Kristina T. Jarvis, Deputy Attorney General.

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge (Respondent Original Licensee). On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

6. Respondent is represented in this proceeding by attorney Derek Shaffer whose address is: 1300 I Street NW, Suite 900, Washington D.C. 20005.

JURISDICTION

7. Accusation No. 7286 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on April 27, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. On July 26, 2023, Complainant filed a First Amended Accusation. A copy of First Amended Accusation No. 7286 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7286. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

9. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

10. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

11. NRP 1826 and NSC 101673 have been cancelled, and the Board confirms that there are no pending allegations or investigations against these licenses, and therefore no future administrative or disciplinary action is contemplated.

CULPABILITY

12. Respondent understands and agrees that the charges and allegations in Accusation No. 7286, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits.

13. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

14. Respondent agrees that its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

15. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action

between the parties, and the Board shall not be disqualified from further action by having considered this matter.

16. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

17. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

18. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970, Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673 issued to Respondents shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7286, attached as exhibit A.

Cost Recovery. No later than 1 YEAR from the effective date of the Decision, Respondent shall pay $11,054.75 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Nonresident Pharmacy Permit NRP 2526, or Nonresident Sterile Compounding Permit No. NSC 101673 until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 7286, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Derek Shaffer. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/2/2024 | 1:23 PM PST

WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, and TW DIAMONDBACK HOLDINGS CORPORATION, dba WEDGEWOOD VILLAGE PHARMACY LLC;

DocuSigned by:
By: MARCY ANN BLISS Marcy Ann Bliss
25DA168EA289425...

Title: CEO
Respondent

I have read and fully discussed with Respondent Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation, dba Wedgewood Village Pharmacy LLC, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 1/4/2024 | 7:34 AM PST

DocuSigned by:
Derek Shaffer
DEREK SHAFFER
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: January 11, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

SA2022301557

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 7286
WEDGEWOOD VILLAGE PHARMACY LLC; **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **MARCY ANN BLISS, CEO;** **JOSEPH COSTA, COO;** **ALISON LYNCH, PIC;** **405 Heron Drive** **Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526,** **Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC;** **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **LUDMILLA MALMBERG, Chairman;** **MARCH ANN BLISS, CEO;** **JOCELYN ROSE STANLEY, Secretary;** **THOMAS J. FORMOLO, Secretary;**	**ACCUSATION**

EDWARD MICHAEL LHEE, Secretary;
ALISON LYNCH, PIC;
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondent.

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Chairman, Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge. On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Ludmilla Malmberg, Chairman,Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Original Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

JURISDICTION

6. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4011 of the Code states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

8. Section 4300 of the Code states in pertinent part:

(a) Every license issued may be suspended or revoked.

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

9. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not

deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

10. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

11. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(c) Gross negligence.

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency....

REGULATORY PROVISIONS

12. California Code of Regulations, title 16, (Regulations) section 1735.2 states in pertinent part:

...

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

...

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

...

(*l*) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

13. Regulations section 1735.3 states in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

...

(2) A compounding log consisting of a single document containing all of the following:

...

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply....

COST RECOVERY

14. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG PREPARATIONS

15. Tacrolimus Ophthalmic Suspension is an eye drop generally prescribed to dogs to treat dry eyes, particularly when caused by low tear production or tears of poor quality. It is a dangerous drug pursuant to Code section 4022.

16. Protirelin is an injectable drug product generally prescribed for horses as a thyrotropin-releasing hormone in order to test for certain metabolic disorders or illnesses. It is a dangerous drug pursuant to Code section 4022.

17. Cyclosporine in MCT oil solution is an eye drop generally prescribed to dogs. It is used to decrease inflammation in the eye and tear glands and increase tear production. It is a dangerous drug pursuant to Code section 4022.

18. Edetate Disodium (EDTA) is a chelating agent generally prescribed to treat corneal ulcers in dogs, cats, and horses. It is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

19. Respondents own and operate a nonresident pharmacy which also possesses a nonresident sterile compounding pharmacy permit, and is located in the State of New Jersey.

20. On or about April 1, 2021, due to a change in the ownership structure of certain parent corporations that own the corporations that own Respondent Original Licensee, successor licensees, both a nonresident pharmacy permit and a nonresident sterile compounding pharmacy permit, were issued to the same immediate ownership structure. Nearly all of the immediate owners and officers of Respondent Original Licensee remained with Respondent Successor Licensee. The conduct set forth in this accusation came to the attention of the Board due to the change of ownership inspection that is required by pharmacy law. Therefore, all of the actions were taken on dates on which Respondent Original Licensee was the owner and operator of the pharmacy. However, since the immediate ownership structure did not change, the owners and operators of Respondent Successor Licensee are responsible for the actions of Respondent Original Licensee.

21. Respondents specialize in veterinary compounding.

22. On January 1, 2017, the Board's sterile compounding regulations became effective.

23. In 2017, Board inspector S.P. issued a written warning to Respondents due to Respondents issuing many of its drug preparations extended beyond use dates (BUDs) without the appropriate data to support those BUDs.

24. In 2018, and again in 2020, during inspections of Respondents facility, Board inspector S.P. discussed with Respondents the documentation Respondents needed to provide, obtain, or test for, in order determine and assign extended BUDs and noted that Respondents had not obtained, tested for, or provided this documentation such that the extended BUDs were still inappropriate.

25. After the 2020 inspection, the Board issued a citation to Respondents for providing 120-day extended BUDs without having the tests and studies required to support the extended BUDs.

///

26. On and between approximately March 17, 2021, and May 28, 2021, Board Inspector M.V. conducted a change of ownership inspection regarding Respondents as discussed in additional depth, above. Due to the COVID-19 pandemic, the inspection was conducted remotely via records review. The investigation report is dated March 1, 2022 (March 1, 2022 Inspection Report).

27. On or about March 19, 2021, Board Inspector M.V. requested five specific compounding logs for review, including certificates of analyses, end-product release testing, documentation supporting any extended BUDs assigned to preparations, sample labels, and training records for Respondents' compounding pharmacist and compounding pharmacy technician. M.V.'s review of just these five compounding logs lead to the causes for discipline set forth below.

FIRST CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Dates)

28. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations 1735.2, subdivision (i). The circumstances are as follows:

A. On or about July 1, 2020, Respondents compounded 623 bottles of Tacrolimus 0.03% ophthalmic aqueous suspensions and gave an extended BUD of 160 days. Respondents only had data to support a 45-day BUD for this drug product.

B. On or about November 27, 2020, Respondents compounded 581 bottles of Cyclosporine 2% in MCT oil ophthalmic solutions and gave an extended BUD of 180 days. Respondents only had data to support a 45-day BUD for this drug product.

C. On or about February 8, 2021, Respondents compounded 353 vials of Protirelin Acetate 1mg/ml injectable solution and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for this product.

///

///

D. On or about March 10, 2020, Respondents compounded 53 bottles (15mL) of Edetate Disodium and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for the product.

SECOND CAUSE FOR DISCIPLINE

(Incomplete Compounding Records)

29. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations section 1735.3, subdivision (a)(2). The circumstances are that Respondents' compounding logs reviewed by Board Inspector M.V. failed to list the manufacturers of the drug components Respondents used for compounding.

THIRD CAUSE FOR DISCIPLINE

(Gross Negligence)

30. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (c), in that Respondents committed acts constituting gross negligence when Respondents assigned extended BUDs without having the required data to support those BUDs.

FOURTH CAUSE FOR DISCIPLINE

(Knowingly Making or Signing a False Document)

31. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents knowingly made or signed false documents when Respondents assigned extended BUDs without having the required data to support those BUDs.

FIFTH CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

32. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption when Respondents continued to assign extended

BUDs and ship the compounded drugs to patients without having the required data to support those BUDs.

DISCIPLINARY CONSIDERATIONS

33. On or about June 17, 2021, Citation number CI 2020 90874 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation did not order a fine, it was not appealed, and it is final.

34. On or about June 17, 2021, Citation number CI 2020 89042 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation ordered a $2,500 fine, and required proof of abatement regarding justification for assigning extended BUDs for antibacterial eye ointment. The citation was not appealed and is final.

35. On or about December 5, 2018, Citation number CI 2018 82132 was issued to Respondent Original Licensee's Nonresident Pharmacy permit f or violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

36. On or about December 5, 2018, Citation number CI 2016 73882 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

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37. On or about October 13, 2017, Citation number CI 2017 77042 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Code section 4059.5, subdivision (b), for selling prescription items to individual. S.G. who was not authorized to purchase these items. S.G. represented himself as a physician and Respondent Original Licensee failed to note the discrepancy between S.G.'s address and the address of the physician he was impersonating. The citation ordered a $1,000 fine, it was not appealed, and it is final.

OTHER MATTERS

38. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 2526 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 101673 issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC then Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, and if Ludmilla Malmberg, Marcy Ann Bliss, Joseph Costa, and Alison Lynch are proven to have knowledge of or have participated in the conduct, then each shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Nonresident Pharmacy Permit number NRP 1826, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

2. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 100970, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

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3. Revoking or suspending Nonresident Pharmacy Permit number NRP 2526, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

4. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 101673, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

5. Prohibiting Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Ludmilla Malmberg from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

7. Prohibiting Marcy Ann Bliss from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

8. Prohibiting Joseph Costa from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

9. Prohibiting Alison Lynch from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

10. Ordering Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Marcy Ann Bliss, and Joseph Costa to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

///

11. Taking such other and further action as deemed necessary and proper.

DATED: 4/5/2023

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2023.04.15 07:02:07 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2022301557
Wedgewood Acc.docx

GOVERNMENT CODE - GOV

TITLE 2. GOVERNMENT OF THE STATE OF CALIFORNIA [8000 - 22980] *(Title 2 enacted by Stats. 1943, Ch. 134.)*

DIVISION 3. EXECUTIVE DEPARTMENT [11000 - 15986] *(Division 3 added by Stats. 1945, Ch. 111.)*

PART 1. STATE DEPARTMENTS AND AGENCIES [11000 - 11898] *(Part 1 added by Stats. 1945, Ch. 111.)*

CHAPTER 5. Administrative Adjudication: Formal Hearing [11500 - 11529] *(Heading of Chapter 5 amended by Stats. 1995, Ch. 938, Sec. 22.)*

11521. (a) The agency itself may order a reconsideration of all or part of the case on its own motion or on petition of any party. The agency shall notify a petitioner of the time limits for petitioning for reconsideration. The power to order a reconsideration shall expire 30 days after the delivery or mailing of a decision to a respondent, or on the date set by the agency itself as the effective date of the decision if that date occurs prior to the expiration of the 30-day period or at the termination of a stay of not to exceed 30 days which the agency may grant for the purpose of filing an application for reconsideration. If additional time is needed to evaluate a petition for reconsideration filed prior to the expiration of any of the applicable periods, an agency may grant a stay of that expiration for no more than 10 days, solely for the purpose of considering the petition. If no action is taken on a petition within the time allowed for ordering reconsideration, the petition shall be deemed denied.

(b) The case may be reconsidered by the agency itself on all the pertinent parts of the record and such additional evidence and argument as may be permitted, or may be assigned to an administrative law judge. A reconsideration assigned to an administrative law judge shall be subject to the procedure provided in Section 11517. If oral evidence is introduced before the agency itself, no agency member may vote unless he or she heard the evidence.

(Amended by Stats. 2004, Ch. 865, Sec. 34. Effective January 1, 2005.)

Wickliffe Veterinary Pharmacy Lexington Kentucky

01/10/2024 – Alaska Imposition of Civil Fine

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

In the Matter of:)
)
Wickliffe Veterinary Pharmacy)
)
Respondent)
Case No. 2023-000824

ORDER

The Alaska Board of Pharmacy (Board), having examined the Imposition of Civil Fine, Case No. 2023-000824, regarding License No. #212202, for failure properly disclose license disciplinary history, hereby adopts the Imposition of Civil Fine.

The Board has determined this is a technical violation of professional licensing statutes and regulations, therefore this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 15th day of February, 2024, at Anchorage, Alaska.

ALASKA BOARD OF PHARMACY

By: _____
Board Chair

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

FORM REVISED 5/01/2015

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☒ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 02032	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: veterinary compounding	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FW6350627 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: veterinary

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Wedgewood Pharmacy LLC

Physical Address: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-331-8272 Toll Free # (NAC 639.708, NRS 639.23286): 800-331-8272

Fax: 856-491-4409 Contact Email: licensing@wedgewoodpharmacy.com

Website: www.wedgewoodpharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Alison Lynch

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): ~~N/A~~ Thomas Caldwell 22943

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Wedgewood Holdings Inc

Corporation/Organization Name: Wedgewood Pharmacy LLC

Mailing Address: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 800-331-8272 Email: licensing@wedgewoodpharmacy.com

Contact Person Name: Joe Costa

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President/COO (title) for Wedgewood Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Joseph Costa

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/15/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Costa, President/COO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4/15/2024
Date

Board Use Only	Date Received: 4/17/24	Amount: $500 check 55857

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Wedgewood Pharmacy LLC

NV Pharmacy or Outsourcing facility license # (if applicable): PH02032

Physical Address: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-331-8272 Toll Free # (NAC 639.708, NRS 639.23286): 800-331-8272

Fax: 856-491-4409 Contact Email: licensing@wedgewoodpharmacy.com

Website: www.wedgewoodpharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Alison Lynch

Supervising/Managing Pharmacist NV Pharmacist Registration #: N/A

Name of Person with direct knowledge of compounding procedures: Alison Lynch

Email of Person with direct knowledge of compounding procedures: alynch@wedgewoodpharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 856-832-2302

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
See attached

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
Wedgewood Pharmacy has had extensive stability testing performed by third party labs. These tests include forced degradation studies of the API(s), method suitability and sterility, pH, and container closure effectiveness. Where applicable, antimicrobial effectiveness testing, endotoxin, and subvisible particle testing were also performed.

6. What laboratory performs this additional testing?
Name: See attached
Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Compounded sterile preparations are visually inspected during in-process checks by the pharmacist. Prior to batch, release, injectable solutions in their final container are visually observed utilizing the black/white box and all preparations are dispensed from their final packaging for visual observation.

8. How often do you perform glove fingertip and medial fill testing?

GFS is performed 3X for the initial testing then every 3 months. For sterile compounding personnel,media fills are performed initially and every 3 months thereafter. Those overseeing compounding perform media fills every 6 months.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Employees that fail a glove fingertip or media fill are prohibited from performing sterile compounding until the GFS or media fill is redone and passing results are confirmed. An investigation is also initiated with any OOS for GFS or media fill.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

See attached

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See attached

12. Who performs the sterile compounding process at your facility?

Only aseptic qualified and trained pharmacists and pharmacy technicians perform sterile compounding processes.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The Pharmacist in Charge is ultimately responsible for compliance with sterile compounding SOPs at the pharmacy. The Pharmacist in Charge works in collaboration with the Pharmacist Lab Manager and sterile compounding personnel.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Packages are intended to protect the compounded preparation from temperature extremes, physical damage, and light, if required. Items packaged in glass are wrapped in bubble wrap or similar material and placed in an appropriate sized shipping container. Compounded preparations that require refrigeration are packaged in a cooler with ice bricks and a temperature indicator card. Temperature verification testing is performed quarterly to ensure items requiring refrigerated storage maintain the appropriate temperature range.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? BSCs		
2. Is your BSC or CACI vented 100% to the outside?	☒ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☒ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☒ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☒ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☒ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? See attached		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Employees will participate in a didactic review and written assessment on policies, procedures and practices related to compounding, packaging, deactivating, handling and/or manipulating antineoplastic and/or other HDs, have a visual audit of a practical/hands-on compounding process and an assessment via UV light showing no evidence of contamination or trace evidence of contamination.		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

See attached

2. What sterilization methods are utilized at your facility?

Sterile filtration, dry heat, autoclave, gamma irradiation(contracted vendor)

3. Does your facility utilize biological indicators? ■ Yes ☐ No

4. If yes, describe how they are utilized:

Biological indicators are used to verify the effectiveness of the cycles in the dry heat oven and autoclave.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alison Lynch
Name of Person who Completed the Form

Pharmacist in Charge
Title

Signature (copies or stamps not accepted)

4/10/24
Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

Acetyl-D-Glucosamine in AQ vehicle	Injection Solution	200 mg/ml
Altrenogest In Ethyl Oleate Oil	Injection Solution	225 mg/ml
Altrenogest in Sesame Oil	Injection Solution	150 mg/ml
Chloramphenicol in White Petrolatum	Ophthalmic Ointment	1 %
Chloramphenicol in AQ vehicle	Ophthalmic Solution	1 %
Cidofovir in Artificial Tears	Ophthalmic Solution	0.5 %
Cisplatin in Sesame Oil	Injection Suspension	3.3 mg/ml
Corticotropin in AQ vehicle	Injection Solution	80 units/ml
Corticotropin in AQ vehicle	Injection Solution	40 units/ml
Cyclosporine in White Petrolatum	Ophthalmic Ointment	1 %
Cyclosporine in White Petrolatum	Ophthalmic Ointment	2 %
Cyclosporine in AQ vehicle	Ophthalmic Suspension	1 %
Cyclosporine/Tacrolimus 2%/0.02% in White Petrolatum	Ophthalmic Ointment	2 %
Dexamethasone Phosphate (as Sodium Phosphate) in White Petrolatum	Ophthalmic Ointment	0.1 %
Diclofenac Sodium in White Petrolatum	Ophthalmic Ointment	0.1 %
Edetate Disodium in AQ vehicle	Ophthalmic Gel	2 %
Edetate Disodium in AQ vehicle	Ophthalmic Gel	1 %
Estrone in AQ vehicle	Injection Suspension	5 mg/ml
Fluorouracil in White Petrolatum	Ophthalmic Ointment	1 %
Fluorouracil in White Petrolatum	Ophthalmic Ointment	5 %
Gabapentin in AQ vehicle	Injection Solution	100 mg/ml
Gentamicin (as Sulfate) in White Petrolatum	Ophthalmic Ointment	0.3 %
Guaifenesin Preservative Free in Dextrose 5%	Injection Solution	50 mg/ml
Isoflupredone Acetate in AQ vehicle	Injection Suspension	2 mg/ml
Medetomidine HCl in AQ vehicle	Injection Solution	20 mg/ml
Miconazole in White Petrolatum	Ophthalmic Ointment	1 %
Praziquantel in Sesame Oil	Injection Solution	62.5 mg/ml
PrednisoLONE Acetate in AQ vehicle	Injection Suspension	50 mg/ml
PrednisoLONE Acetate in AQ vehicle	Injection Suspension	25 mg/ml
Prednisone in AQ vehicle	Injection Suspension	40 mg/ml
Reserpine in Propylene Glycol	Injection Solution	2.5 mg/ml
Romifidine HCl in AQ vehicle	Injection Solution	1 %
Sodium Chloride/EDTA 5%/0.5% in AQ vehicle	Ophthalmic Irrigation Gel	5 %

Tacrolimus in White Petrolatum	Ophthalmic Ointment	0.02 %
Tacrolimus in White Petrolatum	Ophthalmic Ointment	0.03 %
Tacrolimus in White Petrolatum	Ophthalmic Ointment	0.2 %
Tacrolimus in White Petrolatum	Ophthalmic Ointment	0.1 %
Tacrolimus in White Petrolatum	Ophthalmic Ointment	0.3 %
Tacrolimus in MCT Oil	Ophthalmic Solution	0.2 %
Tacrolimus in AQ vehicle	Ophthalmic Suspension	0.1 %
Tolazoline (as HCl) in AQ vehicle	Injection Solution	200 mg/ml
Trichlormethiazide/Dexamethasone (as Acetate) 10mg/0.5mg/ml in Propylene Glycol	Injection Solution	10 mg/ml
Voriconazole in Artificial Tears	Ophthalmic Ointment	1 %
Yohimbine (as HCl) in AQ vehicle	Injection Solution	2 mg/ml

Question 6- Labs

1. Pharmetric Laboratory
   11880 28th Street North, Suite 100
   St. Petersburg, FL, 33716
   Ph: 727-209-5778, Fax: 727-573-0535

2. CIAL: Compounder's International Analytical Laboratory
   4760 Castleton Way, Suite A
   Castle Rock, CO 80109
   Ph:800-788-9922

3. Front Range Labs 3985 S Lincoln Ave.
   Loveland, CO 80537
   Ph:970-593-0171

4. ARL Bio Pharma
   840 Research Parkway, Ste. 546
   Oklahoma City, OK 73104
   Ph:800-393-1595

Wedgewood Pharmacy

The enclosed prescription medication is considered a cytotoxic/chemotherapy drug. As such, the following guidelines are recommended for medication handling, administration and disposal.

1. Keep this medication (and all medications) out of reach of children.
2. Wear gloves when handling or administering medication containers and doses. When finished, remove gloves (inside out), place in a sealed plastic bag and discard.
3. Wash hands immediately following removal of gloves.
4. Dispose of cytotoxic/chemotherapy trash, waste and unused medications by first placing in a sealed plastic bag.
5. Dosage forms should not be manipulated if possible (i.e. crushing tablets, opening capsules). If HD dosage forms do require manipulation for a single dose, gloves must be worn, and a plastic bag or pouch must be used to contain any dust or particles generated from being inhaled.
6. If your state does not have a household hazardous waste collection program in your area that accepts medications for destruction, dispose in the municipal trash collection, taking precautions to ensure that children and animals cannot access the unused medication. This method is currently considered safer and more environmentally friendly than flushing down toilets or sinks.

CAUTION: Pregnant women should not handle chemotherapy drugs, clean cages or handle waste from animals during cancer treatment.

While taking chemotherapy medications, your pet's waste (urine, vomit and feces) may be contaminated with chemotherapy medications and will require special handling. Follow your veterinarian's specific recommendations. General handling recommendations include:

Urine Waste

- Encourage pet to urinate on soil where urine will drain quickly.
- Handle and dispose of all other urine the same as chemotherapy waste.
- Discard soiled bedding; do not launder.
- Contaminated surfaces should be washed down gently; not pressure washed.
- Follow these safety precautions during therapy and following therapy for the time specified by your veterinarian or pharmacist; or a minimum of 48-72 hours.

Vomit / Feces:

- Place scooped feces in securely sealed plastic bags before discarding.
- Use similar precautions as for urine.

These precautions will protect you from unnecessary exposure to cytotoxic/chemotherapy medications and waste. Normal handling and interaction with your pet is safe and to be encouraged. Your relationship with them is an important part of their health and well-being.

If you have any questions, do not hesitate to contact your veterinarian or one of our pharmacists at Wedgewood Pharmacy (800-331-8272). You can also log onto to the National Institute of Occupational Safety and Health (NIOSH) website https://www.cdc.gov/niosh/index.htm for further information.

Wedgewood Pharmacy

Administering Hazardous Drugs Safely

The following guidelines are recommended for medication handling, administration and disposal.

1. Keep this medication (and all medications) out of reach of children.
2. Wear gloves when handling or administering medication containers and doses. When finished, remove gloves (inside out) and discard.
3. Wash hands immediately following removal of gloves.
4. Dosage forms should not be manipulated if possible (i.e. crushing tablets, opening capsules). If HD dosage forms do require manipulation for a single dose, gloves must be worn, and a plastic bag or pouch must be used to contain any dust or particles generated from being inhaled.
5. If your state does not have a household hazardous waste collection program in your area that accepts medications for destruction, dispose in the municipal trash collection, taking precautions to ensure that children and animals cannot access the unused medication. This method is currently considered safer and more environmentally friendly than flushing down toilets or sinks.

CAUTION: Men and women who are actively trying to conceive, women who are pregnant or may become pregnant and women who are breast feeding must use extra care and follow these safe medication handling practices as many HDs present reproductive and developmental hazards.

Normal handling and interaction with your pet is safe and to be encouraged. Your relationship with them is an important part of their health and well-being.

If you have any questions, do not hesitate to contact your veterinarian or one of our pharmacists at Wedgewood Pharmacy (800-331-8272). You can also log onto to the National Institute of Occupational Safety and Health (NIOSH) website https://www.cdc.gov/niosh/index.htm for further information.

Question 10

Personnel will complete the Sterile Compounding and Aseptic Technique course, or equivalent ACPE-approved course,

Demonstrate proficiency in the theoretical principles and practical, hands-on skills of sterile manipulations and in achieving and maintaining appropriate environmental conditions.

Read 797 and complete a written assessment

Complete a didactic review of theoretical principles, practical skills, policies, practices, and procedures related to sterile preparation compounding core competencies, including, but not limited to,

· hand hygiene

· garbing

· cleaning and disinfection,

· calculations, measuring and mixing,

· Aseptic technique,

· achieving and/or maintaining sterility and apyrogenicity,

· use of equipment,

· documentation of the compounding process

· principles of direction of the HEPA-filtered unidirectional airflow within the ISO Class 5 area,

· proper use of C-PECs and

· principles of movement of materials and personnel within the compounding area and

Demonstrate knowledge via successful completion of written physical and/or electronic assessment(s) and proficiency via a hands-on demonstration of skills.

- Be visually observed while performing hand hygiene and garbing procedures;

Question 10

- Complete gloved fingertip and thumb sampling and
- Perform media fill tests to assess their sterile technique
- Observed for competency
- Potency test

Question 11

Primary engineering controls are cleaned/disinfected daily. Cleaning will be performed from back to front so that contaminants are moved out of the LAFW/BSC. Solution alternate according to schedule and include the following:

- Decon-Quat Ammonium Solution – Clean/disinfect 10-minute contact time
- Decon-Phene High pH Phenolic Germicidal Detergent with Organic Soil Tolerance - Clean/disinfect 10-minute contact time
- Decon-Cycle Low pH Phenolic Germicidal Detergent/disinfectant – Clean/disinfect 10-minute contact time

Once/week Primary engineering controls are cleaned/disinfected utilizing a sporicidal agent

- Peridox Sporicidal Disinfectant/Cleaner – 3-minute contact time and is followed with a wiping of the interior of the PEC with Sterile IPA – Texwipe 70% sterile IPA

LAFW/BSC will be cleaned routinely throughout the compounding process and in between preparations according to procedure.

- Cyquanol Quaternary Ammonium and Ethanol Disinfectant/cleaner followed by a wiping of the interior of the PEC with Texwipe Sterile 70% IPA
- HD- Peridox Sporicidal Disinfectant/Cleaner – 3-minute contact time and is followed with a wiping of the interior of the PEC with Sterile IPA – Texwipe 70% sterile IPA.

Secondary engineering controls are cleaned/disinfected daily. Cleanroom complexes are cleaned complex in order form the cleanest to the least clean areas (i.e. Iso Class 5 area(s), then the ISO 7 buffer area(s), then the ISO class 7 or 8ante area, and the ISO class 8 gowning area last.

During weekly cleans the order of cleaning within the buffer room is interior of the LAFW/BSC, ceiling, walls, exterior of the LAFW/BSC, all surfaces/carts, and lastly the floor.

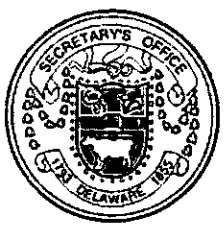
The cleanroom complex(es) are cleaned beginning from the furthest point from the door working towards the door starting with the ceiling, then the walls, then the surfaces/carts, and lastly the floor.

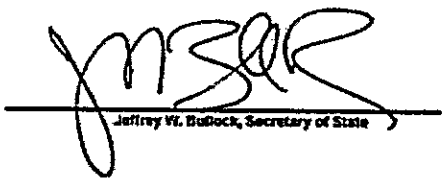
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "WEDGEWOOD VILLAGE PHARMACY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF MARCH, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





5944344 8300

SR# 20241174280

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203115229

Date: 03-26-24

Date: 8-23-2023
Time entered: 11:00am
Time departed: 12:15pm

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: Wedgewood Pharmacy
Address: 405 Heron Dr. Ste 200 Swedesboro, NJ 08085
Name and registration number of pharmacist-in-charge:
Alison Lynch 28RI02410600
(If the Pharmacist-in-Charge is not present, give the name and registration number of the Registered Pharmacist (R.P.) on duty.)

The following deficiencies have been noted:

No deficiencies noted

Upon further review additional citations can be issued. A narrative report including final citations and area of concerns will be provided to the Board

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions; if any.

COMMENTS:

(Signature of the Pharmacist identified above)

BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

WEDGEWOOD VILLAGE PHARMACY, LLC
ALISON LYNCH
405 Heron Drive, Suite 200
Swedesboro NJ 08085

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy
Restricted
Standard Retail Pharmacy
Community

06/12/2023 TO 06/30/2024
VALID

28RS00316800
LICENSE/REGISTRATION/CERTIFICATION #

Signature of Licensee/Registrant/Certificate Holder

Cari Fais
ACTING DIRECTOR

Corporate Information
Wedgewood Pharmacy LLC
Wedgewood Connect LLC

Officers:

President:	Joseph Costa
CFO & Treasurer	Maria Kraus
Secretary	Marcy Bliss

Parent Companies:

Wedgewood Holdings Inc. (100% owner of Wedgewood Pharmacy LLC)
Specialty Pharma III Inc. (100% owner of Wedgewood Holdco Inc)
Specialty Pharma II Inc. (100% owner of Specialty Pharma III Inc.)
Specialty Pharma I Inc. (100% owner of Specialty Pharma II Inc.)
Specialty Pharma Holdings LP (100% owner of Specialty Pharma I Inc.)

Address:

405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Officers:

President & COO:	Joseph Costa
CFO:	Maria Kraus
CEO & Sec.:	Marcy Bliss

Directors:

Marcy Bliss
Sofia Gerard
Dennis Maloney
Kevin Vasquez
David Kamenetzky
Peter Berweger

Shareholders:

There are no individual shareholders in Wedgewood Connect/Village Pharmacy as both entities are member managed limited liability companies.

All shares in Wedgewood Holdings Inc. are held by Specialty Pharma III Inc.

Marcy Bliss, Maria Kraus and Joseph Costa have served as officers at the following pharmacy locations:

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
7631 E. Indian School Road, Suite 105
Scottsdale, AZ 85251

ZooPharm LLC (now closed)
3131 Grand Ave., Unit C, Laramie, WY 82070

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Wedgewood Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH02032

Physical Address 405 Heron Drive

City Swededboro State NJ Zip 08085

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (800) 331-8272 Website https://www.wedgewoodpharmacy.com/

Licensing Company Email Licensing@wedgewoodpharmacy.com

Section 2: Personal Information

First Thomas Middle _____ Last Caldwell

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]unt club ln

City media State pa Zip 19063

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Philadelphia College of Pharmacy and Science		09/90-05/95	
Address	**City**	**State**	**Zip**
600 S. 43rd St	Philadelphia	PA	19104-449
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
St. James		09/86-6/90	
Address	**City**	**State**	**Zip**
18 East 21st Street	Chester	PA	19013
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/08 to present	[redacted]hunt club ln	media	pa	19063
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Wedgewood Pharmacy			01/12-present	
Business Address		**City**	**State**	**Zip**
405 Heron Dr		swedesboro	NJ	08005
Phone	**Title**		**Number of Employed Hours**	
(800) 331-8272	Pharmacist Manager		25,000	
Description of Duties				
Management of dispensing pharmacist staff				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Thomas Caldwell, **certify that as the designated representative for**

Wedgewood Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Thomas Caldwell

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 4/9/24

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

THOMAS CALDWELL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date 4/9/24

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Gloucester

I, Thomas Caldwell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature **Date** 4/9/24

Subscribed and Sworn to before me this 9th day of April.

Samantha Botnick

Notary Public Signature

SAMANTHA L BOTNICK NOTARY PUBLIC STATE OF NEW JERSEY MY COMMISSION EXPIRES JUNE 25, 2025

Samantha L Botnick
NOTARY PUBLIC
State of New Jersey
ID # 50130085
My Commission Expires
June 25, 2025

(Seal)

NEW JERSEY DIVISION OF
CONSUMER AFFAIRS



Cari Fais
Acting Director
Read Bio

License Information

Accurate as of April 15, 2024 3:09 PM

Return to Search Results

Name: WEDGEWOOD VILLAGE PHARMACY LLC

Address: Swedesboro,NJ

Profession/License Type: Pharmacy,Pharmacy

License No: 28RS00316800

License Status: Active

Status Change Reason:

Issue Date: 9/1/1981

Expiration Date: 6/30/2024

SPL: New Jersey

Board Action: YES*
Please visit DCA's website to see the final disposition documents.

* A "YES" in the "Board Action" field indicates that the licensee has a public record of some form of action on file with the Board/Committee. Board actions may come in the form of a Consent Order, Cease and Desist Order, Interim Order, Reprimand, a finalized Uniform Penalty Letter, agreed upon Settlement Letter or Final Order. In some instances, "Yes" will represent that a public record of a pending matter such as an Administrative Complaint or a Provisional Order of Discipline may have been filed with the Board/Committee. Such documents represent the filing of allegations by the Attorney General, and do not represent a finding of misconduct until the matter is adjudicated by the Board. Contact the Board/Committee directly to obtain a copy of such documents.

To obtain copies of such documents not readily available on the "Actions (Disciplinary and Other)" page of the Board's website, or if no documents are displayed below, please contact the Board directly at NJBOPVerifications@dca.lps.state.nj.us.

Documents

No Public Documents

Division
Division Home
Consumer Protection
Licensing Boards
File a Complaint
Adoptions & Rule Proposals
Internship Opportunities

Department
OAG Home
Contact OAG
FAQ OAG
OAG News
Services A to Z
Employment

State
NJ Home
Services A-Z
Departments/Agencies
FAQs

Legal
Legal Statement
Privacy Notice
Accessibility Statement

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More information about RSS feeds.

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OPRA | Open Public Records

2646

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER. WITH A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL

DIVISION OF CONSUMER AFFAIRS

CONTROLLED DANGEROUS SUBSTANCES

CDS REGISTRATION NUMBER

D03225200

WEDGEWOOD VILLAGE PHARMACY, LLC
WEDGEWOOD VILLAGE PHARMACY, LLC
405 Heron Drive, Suite 200
Swedesboro NJ 08085

IS REGISTERED AS: **CDS Pharmacy** FOR SCHEDULES **2 3 4 5**

10/25/2023 TO 10/31/2024	FW6350627	28RS00316800
VALID	DEA NO.	LICENSE/REGISTRATION/CERTIFICATION #

SIGNATURE OF REGISTRANT

Cari Fais
ACTING DIRECTOR

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW6350627	05-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-13-2022

WEDGEWOOD VILLAGE PHARMACY
405 HERON DR STE 200
SWEDESBORO, NJ 080851749

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW6350627	05-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-13-2022

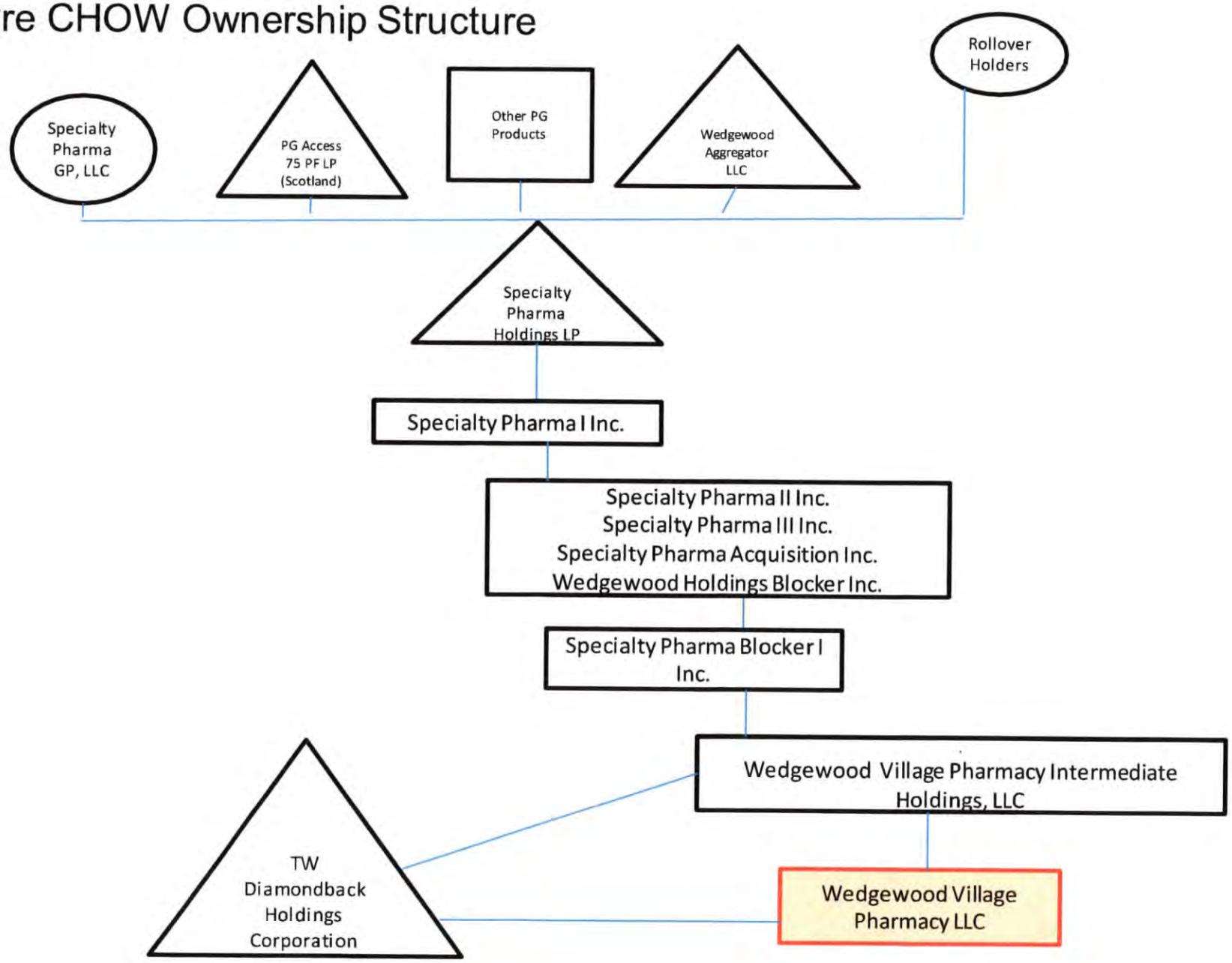
WEDGEWOOD VILLAGE PHARMACY
405 HERON DR STE 200
SWEDESBORO, NJ 080851749

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

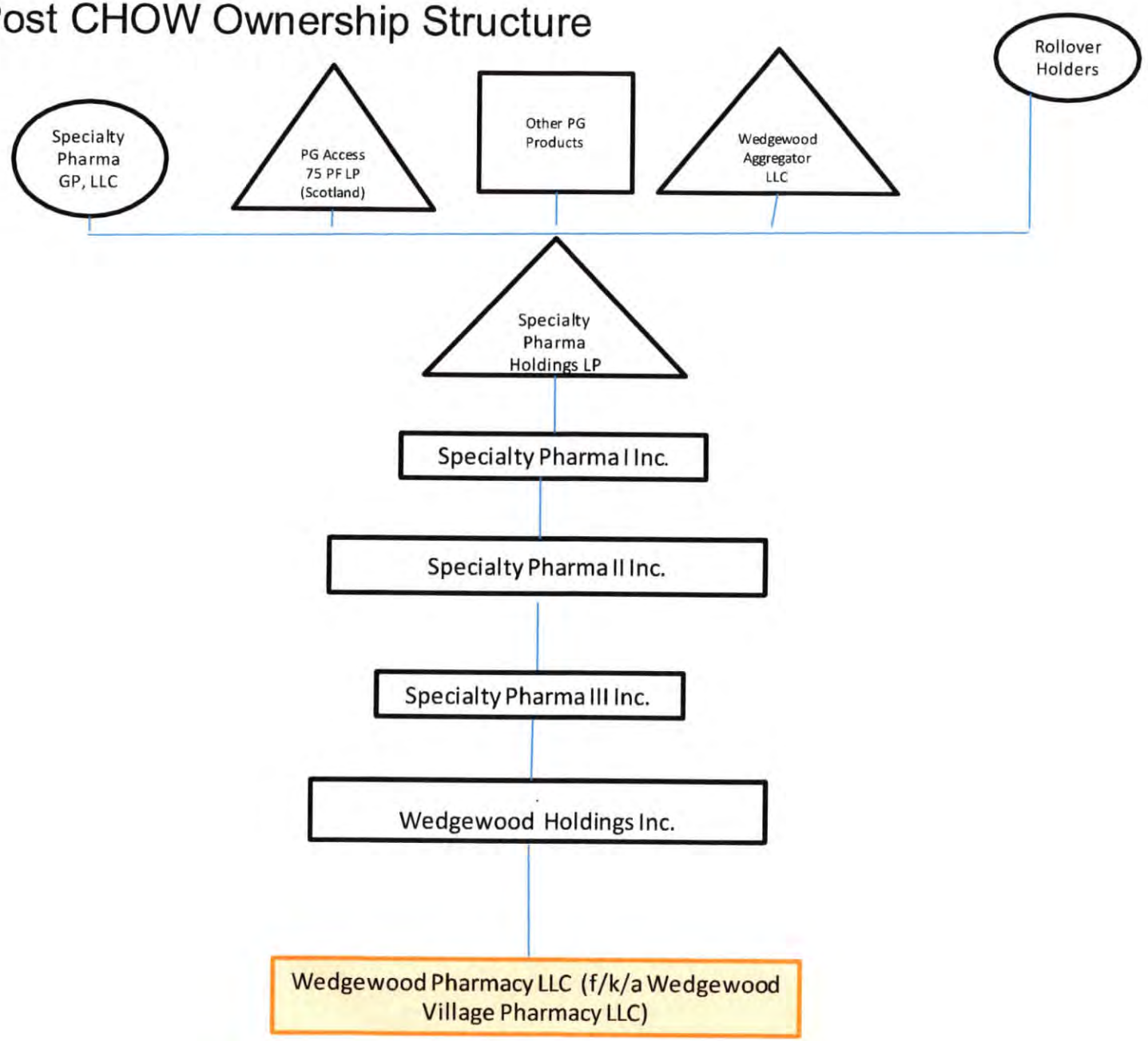
THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Pre CHOW Ownership Structure



Post CHOW Ownership Structure



Section 3: History of Company

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?

Wedgewood Pharmacy LLC

The list includes prior matters that have previously been reported to the Board in an effort to provide full transparency with the application.

03/19/2015 – MN/MI/AL Consent Orders

On March 19, 2015, Wedgewood entered into a consent order with the Minnesota Board of Pharmacy (*"Minnesota Consent Order"*). Wedgewood subsequently entered into consent orders with the Michigan Department of Licensing and Regulatory Affairs (*"Michigan LARA"*) and the Alabama Board of Pharmacy ("Alabama BOP") to resolve "sister state" actions that arose out of the Minnesota Consent Order.

The basis for the Minnesota Consent Order are as follows:

Acting on a reasonable and good-faith interpretation of Minnesota law, Wedgewood from its NJ location, dispensed compounds to licensed veterinarians in Minnesota, pursuant to a veterinarian's order for office use. The Minnesota Board asserted that Wedgewood needed a wholesale license to engage in this activity. For the purposes of settlement only, Wedgewood entered into the Minnesota Consent Order whereby it agreed to a $10,000 civil penalty but admitted no wrongdoing.

Wedgewood subsequently entered into a consent order with the Michigan LARA to resolve a "sister state" action brought by Michigan based on the Minnesota Consent Order. Wedgewood entered into a similar consent order with the Alabama BOP to resolve a sister state action brought by Alabama based on the Minnesota Consent Order. There was no finding in the Michigan or the Alabama Consent Order that Wedgewood violated any provisions of Michigan or Alabama state law outside of these states' prohibitions on sister state actions.

10/22/2015 – New Jersey Consent Agreement

On October 22, 2015, Wedgewood Village Pharmacy, Inc., entered into a Consent Agreement with the New Jersey Board of Pharmacy resolving a dispute between the parties on the application of "beyond use dating" regulations for sterile compounds.

This is the same order that is referenced on the Swedesboro, NJ facility's home license however, per the terms of the Agreement, it is not to be construed as discipline and any reimbursement paid ta the Board is not considered a fine or other sonction.

10/13/2017 – California Citation & Fine

Issued as a result of an investigation by the CA BOP into an unlicensed individual who fraudulently set up an account with Wedgewood as a veterinarian using valid prescriber license information he acquired unlawfully. An administrative citation was issued and Wedgewood paid a nominal fine.

07/20/2018 - DEA Memorandum of Agreement

While Wedgewood does not consider there to be a restriction on its handling of CDS or disciplinary action, however, out of an abundance of caution, Wedgewood is disclosing the following:

As a condition of issuing Wedgewood located in Swedesboro, New Jersey a DEA manufacturer registration, Wedgewood and the DEA entered into a Memorandum of Agreement ("MOA") for a period of five years (until July 20, 2023) during which Wedgewood agreed not to use the DEA manufacturer license to manufacture or distribute controlled substances for human use. Wedgewood obtained a DEA manufacturer registration for the sole purposes of providing controlled substance compounds solely for veterinarians to use for office use.

12/5/2018 – California Citation

The California Board of Pharmacy issued a non-disciplinary, Administrative Citation with no penalty or fine based on a California Board inspector's interpretation of California regulations. In the Inspector's opinion, providing a 15ml ophthalmic container to a veterinarian for office use exceeded the "reasonable quantity" limitation for office use compounds.

Wedgewood discontinued sales of all 15ml ophthalmic container for office use to California veterinarians. The Board issued a Close Out letter on March 1, 2019. No penalty or fine was assessed.

6/17/2021 – California Citation & Fine

Received notification of a non-disciplinary, Administrative Citation which was finalized on 07/29/2021. A fine was paid as part of the final citation. The basis for the citation was that Wedgewood did not have the necessary data to support the "beyond use dates" Wedgewood used.

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

On February 21, 2024, the California Board of Pharmacy (the "Board") approved a Stipulated Settlement and Disciplinary Order for Public Reproval entered into with Wedgewood Village Pharmacy LLC relating to claims made by the Board regarding assignment of unsupported beyond use dates and other matters. The Order became effective on March 22, 2024 and Wedgewood agreed to pay the Board $11,054.75 as reimbursement of its costs in connection with this matter.

Rachel Taggs
Sr. Compliance Specialist
Wedgewood Pharmacy

MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

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Metro and Non-Metro; 800-627-3529
E-Mail Address: Pharmacy.Board@state.mn.us
Web Site: www.pharmacy.state.mn.us

MAR 1 9 2015

PERSONAL & CONFIDENTIAL

March 16, 2015

Gregory P. Bulinski
Attorney
Bassford Remele
33 South Sixth Street, Suite 3800
Minneapolis, MN 55402-3707

Re: In the Matter of Wedgewood Pharmacy
License No. 262173

Dear Mr. Bulinski,

Enclosed and served upon you in the above-referenced matter is the fully executed Stipulation and Consent issued by the Board of Pharmacy.

Sincerely,

Cody Wiberg

Cody Wiberg, Pharm D, MS, RPh
Executive Director

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remele and Rachael G. Pontikes, Esq., of Dunne Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III, above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MARGY ELISS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

IN THE MATTER OF:	
WEDGEWOOD VILLAGE PHARMACY, LLC	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
Non-Resident Pharmacy Permit Number: 112625	**CASE NO: 16-L-0066**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Wedgewood Village Pharmacy, LLC ("Wedgewood") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Wedgewood through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Wedgewood has violated the "sister-state" provisions of Alabama law as set out in the Statement of Charges.

2. Wedgewood shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Wedgewood expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975),

§34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Wedgewood further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Wedgewood hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Wedgewood acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Wedgewood's permit, including, but not limited to revocation.

6. Wedgewood acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wedgewood acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 6th of June, 2017.

WEDGEWOOD VILLAGE PHARMACY, LLC

BY: [signature]

ITS: President & CEO

[signature]

Jennifer Clark, attorney for Wedgewood Village Pharmacy, LLC

DONE this the ____ of 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: Buddy Bunch

Buddy Bunch, R.Ph., President

By: [signature]

James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF: WEDGEWOOD VILLAGE PHARMACY, LLC Non-Resident Pharmacy Permit Number: 112625	BEFORE THE ALABAMA STATE BOARD OF PHARMACY CASE NO: 16-L-0066

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Wedgewood Village Pharmacy, LLC
406 Heron Drive
Suite 200
Swedesboro, New Jersey 08085

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on _____ _____, 2016 at _____m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Wedgewood Village Pharmacy, LLC (Wedgewood) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Wedgewood has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Stipulation and Consent Order by the Minnesota Board of Pharmacy on January 4,

2015 attached hereto as Exhibit "A" and/or the Facts set out therein that you shipped drugs to licensed veterinarians in Minnesota without patient specific prescriptions nor the required license to do so.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon the Consent Order entered by the State of Michigan Board of Pharmacy on April 13, 2016 as a result of the filing of an Administrative Complaint, these documents being attached hereto as Exhibits "B" and "C".

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FOUR

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of

the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the _____ day of _____, 2016.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT "A"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goelz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullock, Esq., of Hazelford Rennels and Rachael O. Pontikes, Esq., of Dunn Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board impose a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedures:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

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c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

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18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICE

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 3. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MARCY BLISS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT "B"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

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CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullinski, Esq., of Bassford Remele and Rachael C. Pontikes, Esq., of Dunne Morris.

EXHIBIT A page 1 of 7

III.

FACTS

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IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

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9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

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10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

EXHIBIT A page 3 of 7

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

EXHIBIT A page 4 of 7

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

EXHIBIT A page 5 of 7

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

EXHIBIT A page 6 of 7

CONSENT:

MARGY ELSE, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT A page 7 of 7

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Fitzgerald (P45884)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2016

AGREED TO BY:

Alison Lyndy, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 3/31/16

Alan T. Rozalski (P46660)
Attorney for Respondents
Dated: 3/31/2016

EXHIBIT "C"

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the matter of

WEDGEWOOD VILLAGE PHARMACY INC.
License Number: 53-01-008041 File Number: 53-15-137238

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs (Complainant) by Kim Gaedeke, Acting Director, Bureau of Health Care Services, files this Complaint against Wedgewood Village Pharmacy Inc. (Respondent Pharmacy) as follows:

1. The Michigan Board of Pharmacy (Board) is an administrative agency established by the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq. Pursuant to section 17768 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent Pharmacy is licensed to practice as a pharmacy in the state of Michigan and has an address of record with Complainant of Swedesboro, New Jersey.

3. On January 21, 2015, the Minnesota Board of Pharmacy (Minnesota Board) executed a Stipulation and Consent Order which ordered Respondent Pharmacy

to pay a $10,000.00 civil penalty. The action was based on Respondent Pharmacy not being licensed as a drug wholesaler by the Minnesota Board and shipping drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. A copy of the Stipulation and Consent Order, marked Exhibit A, is attached and incorporated

COUNT I

The action by the Minnesota Board, as set forth above evidence a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty and constitutes a violation of section 17768(2)(d) of the Public Health Code, supra.

Complainant requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq.

Pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Kim Goedeke, Acting Director, Bureau of Health Care Services, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

Pursuant to section 16231(9) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

DATED: 07/24/2015

Kim Geedeke, Acting Director
Bureau of Health Care Services

Attachment

This is the final page of an Administrative Complaint in the matter of Wedgewood Village Pharmacy Inc., File Number 53-15-137239, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

DWC

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

Wedgewood Village Pharmacy, Inc.
License No. 58-01-008041

Complaint No. 58-15-137238

CONSENT ORDER AND STIPULATION

CONSENT ORDER

An administrative complaint was filed with the Disciplinary Subcommittee of the Board of Pharmacy on July 24, 2015, charging Wedgewood Village Pharmacy, Inc. (Respondent) with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended, MCL 333.1101 *et seq.*

The parties have stipulated that the Disciplinary Subcommittee may enter this consent order. The Disciplinary Subcommittee has reviewed the stipulation contained in this document and agrees that the public interest is best served by resolution of the outstanding complaint. Therefore, the Disciplinary Subcommittee finds that the allegations of fact contained in the complaint are true and that Respondent has violated section 17768(2)(d) of the Public Health Code.

Accordingly, for this violation, IT IS ORDERED:

Respondent is FINED $500.00 (Five Hundred Dollars) to be paid by check, money order or cashier's check made payable to the State of Michigan (with complaint number 58-15-137238 clearly indicated on the check or money order), and

shall be payable within 60 days of the effective date of this order. The timely payment of the fine shall be Respondent's responsibility. Respondent shall mail the fine to: Sanction Monitoring, Bureau of Professional Licensing, Enforcement Division – Compliance Section, Department of Licensing and Regulatory Affairs, P.O. Box 30169, Lansing, Michigan 48909.

This order shall be effective on the date signed by the Chairperson of the Disciplinary Subcommittee or the Disciplinary Subcommittee's authorized representative, as set forth below.

Signed on 4-13-16

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

The parties stipulate as follows:

1. Respondent does not contest the allegations of fact and law in the complaint. Respondent understands that, by pleading no contest, it does not admit the truth of the allegations but agrees that the Disciplinary Subcommittee may treat the allegations as true for resolution of the complaint and may enter an order treating the allegations as true.

2. Respondent understands and intends that, by signing this stipulation, it is waiving the right under the Public Health Code, rules promulgated under the Public Health Code, and the Administrative Procedures Act of 1969, 1969 PA 306,

as amended, MCL 24.201 *et seq.*, to require the Department to prove the charges set forth in the complaint by presentation of evidence and legal authority, and to present a defense to the charges before the Disciplinary Subcommittee or its authorized representative. Should the Disciplinary Subcommittee reject the proposed consent order, the parties reserve the right to proceed to hearing.

3. The Disciplinary Subcommittee may enter the above Consent Order, supported by Board conferee Patti Smeelink, R.Ph. Ms. Smeelink or an attorney from the Licensing and Regulation Division may discuss this matter with the Disciplinary Subcommittee in order to recommend acceptance of this resolution.

4. Conferee Smeelink and the parties considered the following factors in reaching this agreement:

A. Respondent has fully cooperated in this matter and since initially licensed in 2004, Respondent has never had any disciplinary action taken against its Michigan Pharmacy license prior to this incident.

B. Respondent timely reported the Minnesota Board of Pharmacy Stipulation and Consent Order to the Department.

C. The violation of MCL 388.17768(d)(2) as alleged in the Complaint is based solely on a "sister-state" action taken against Respondent's Pharmacy license by the Minnesota Board of Pharmacy that was based on Respondent's former practice in 2012 of dispensing compounded veterinary medications for office-use to licensed veterinarians in Minnesota, which according to the Minnesota Board of Pharmacy, required a wholesaler's license. However, this practice did not implicate Respondent's practice of pharmacy in the State of Michigan and Respondent has not been found to have violated the Michigan Public Health Code or Board of Pharmacy Administrative Rules, except as provided herein.

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Elizondo

Kelly K. Elizondo (P45584)
Assistant Attorney General
Attorney for Complainant
Dated: 5-1-2016

AGREED TO BY:

Alison Deich, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 3/31/16

Alan T. Rogalski (P44550)
Attorney for Respondent
Dated: 3/31/2016

DM\6772748.1

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street 5th Floor
P.O. Box 45029
Newark, New Jersey 07101

By: Megan Cordoma
Deputy Attorney General
Tel. No. (973) 648-4730

FILED
OCT 22 2015
BOARD OF PHARMACY

STATE BOARD OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF
THE REGISTRATION OF

WEDGEWOOD VILLAGE PHARMACY, INC.
Registration No.:28RS00316800

TO OPERATE A PHARMACY
IN THE STATE OF NEW JERSEY

Administrative Action

CONSENT ORDER

This matter was opened to the New Jersey Board of Pharmacy ("the Board") upon receipt of reports of inspection of the facility at Wedgewood Village Pharmacy, Inc. ("Wedgewood") which occurred on November 14 and 15, 2012. The reports document potential violations of the Board's regulations regarding sterile compounding. Wedgewood engages in high risk sterile compounding.

Among other things, the inspection reports highlighted routine professional practices suggesting that thousands of units of medication were dispensed with disregard for the following regulatory requirements:

- Use-by dates exceed 30 days after preparation in violation of N.J.A.C. 13:39-11.11.

- Failure to include date and time of preparation on prescription labels in violation of N.J.A.C. 13:39-11.10(a)(1).

- Failure to include the use-by date and use-by time on prescription labels as required by N.J.A.C. 13:39-11.10(a)(7).

No evidence of contamination was found. Wedgewood denies the allegations of violations and has been fully cooperative with the Board's investigation. There have been significant changes in management of Wedgewood since the time of the events in question. The pharmacy permit holder at the time of these events is now deceased and his wife now holds the permit. Wedgewood has agreed to replace the registered pharmacist-in-charge. Wedgewood represents that it is now in compliance with New Jersey statutes and regulations and with the USP guidelines. Wedgewood further represents that 100% of all sterile compounds are currently being tested for sterility and that all use-by dates are properly supported. Accordingly, the Board has determined that the monitoring requirements imposed herein are sufficient to protect the public health, safety and

welfare.

The parties, having agreed to resolution of this matter without formal proceedings, and Wedgewood, having agreed and given voluntary consent to the within order and waiving any right to a hearing, and the Board finding the within disposition adequately protective of the public health, safety, and welfare, and other good cause having been shown;

IT IS THEREFORE on this 22nd day of OCTOBER, 2015,

ORDERED AND AGREED that

1. Wedgewood shall contract with a third-party monitor (the "Monitor") pre-approved by the Board to review all compounding operations of the pharmacy. For the purposes of this Order, LDT Health Solutions, Inc. is an approved Monitor. Within 30 days of the entry of this Order, the Monitor shall furnish the Board directly with a report which demonstrates review of all processes and procedures, and attests to compliance with all Board regulations and USP standards. Wedgewood shall conduct environmental testing, pressure differential monitoring, and air and surface sampling for bacteria and fungi and make these test results available to the Monitor prior to the Monitor issuing its report and directly to the Board. Wedgewood shall continue to contract with the Monitor and the Monitor will submit reports directly to the Board on the first day of each month until the Monitor

reports directly to the Board that Wedgewood has complied with all recommendations made by the Monitor and is operating in full compliance with all Board regulations and USP standards. All costs associated with the monitoring outlined in this Order shall be the responsibility of, and paid directly by, Wedgewood.

2. Within 30 days of the entry of this order, Wedgewood shall appoint a new pharmacist-in-charge and shall ensure that a pharmacist with sterile compounding expertise (either the pharmacist-in-charge or another employee) directly supervises the daily sterile compounding operations to further ensure the quality and integrity of their products. "Directly supervise" for the purpose of this paragraph means ensure that all proper checks and balances are being performed during the compounding process; help identify and eliminate errors and mistakes; ensure training and testing of personnel testing is occurring; and generally help to ensure that proper aseptic technique is being used to help implement a Quality System and Environment to produce compounded sterile product.

3. Prior to hiring any pharmacist-in-charge or pharmacist to directly supervise daily sterile compounding operations, Wedgewood shall ensure that the individual is competent and that his/her license is not restricted in such a way as to preclude them from fulfilling their job responsibilities.

Wedgewood shall not hire an individual to be pharmacist-in-charge or to directly supervise the daily sterile compounding operations if Wedgewood is aware that the individual is subject to a pending Board investigation.

4. Wedgewood agrees to pay the Board the sum of $500,000.00 in two equal installments due on or before November 31, 2015 and December 31, 2015. This payment will reimburse the Board for attorney's fees and investigative costs and the remainder will be applied toward the Board's ongoing efforts to inspect, investigate and educate pharmacies involved in sterile compounding. Wedgewood and the Board acknowledge and agree that the payment described herein is not a fine, sanction, warning letter or penalty, or payment in lieu thereof. Payment shall be made by bank check, money order, wire transfer or credit card made payable to the New Jersey Board of Pharmacy.

5. This Consent Order shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability of the pharmacy.

NEW JERSEY STATE BOARD OF PHARMACY

By: Thomas F.X. Bender, Jr. RPh
Thomas F.X. Bender,
R.Ph., President

I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.

Ludmilla P Malmberg
Ludmilla P Malmberg, Owner
and Permit Holder of
Wedgewood Village Pharmacy

Consent as to form and entry:

Angelo Cifaldi
Angelo Cifaldi, Esq.
Attorney for
Wedgewood Village Pharmacy

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 13, 2017

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- November 12, 2017: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 27, 2017: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 12, 2017: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 12, 2017.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Ericka Busby
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7731

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 27, 2017 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 12, 2017 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 574-7924.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	$1,000.00

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: November 12, 2017

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	**A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board**	**$1,000.00**

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: November 12, 2017

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: WEDGEWOOD VILLAGE PHARMACY LLC NRP 1826 Respondent	Citation Case No : CI 2017 77042 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2017 77042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On October 13, 2017, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7017 0530 0001 1516 2087

I declare under penalty of perjury that the forgoing is true and correct.

Executed on October 13, 2017, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NRP 1826

Citation Number : CI 2017 77042

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☑ I contest the Citation and request an Office Conference.

Check One:

☑ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: Mary Ann Bliss

Signature: Mary Ann Bliss Dated: 10/26/17

Address of Service: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: (Business) (856) 832-1303 Residence: (609) 320-5050

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

UPS
1Z 54E 746 01
0470 45 82
Tracking #
10/26/17 3:11 pm

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 23, 2017

Wedgewood Village Pharmacy
Attention: Alison Lynch
405 Heron Dr., Ste. 200
Swedesboro, NJ 08085

RE: Complaint Investigation CI 2016 72146

Dear Pharmacist-in-Charge:

The Board of Pharmacy has completed its investigation of Wedgewood Village Pharmacy.

As a regulatory agency, when conducting an investigation, the Board must adhere to violations prohibited in pharmacy law. Specifically, the information and documentation obtained during the course of an investigation must clearly demonstrate that a violation of pharmacy law occurred.

The Board's analysis of the information and documentation received did not identify sufficient evidence to determine that a violation of pharmacy law occurred. Accordingly, the Board is closing the matter and will be taking no action against the pharmacy or its licensees.

Although we are closing this matter, please be advised that it is your professional responsibility to assure compliance with all pharmacy laws.

We would like to thank you for your cooperation and assistance. If you should have any questions, please contact the Board at the above address or telephone number.

Sincerely,

VIRGINIA K. HEROLD
Executive Officer

By

Tina Rojas
Complaint Unit Analyst

Visit our website at www.pharmacy.ca.gov

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
NEW JERSEY DIVISION
CAMDEN RESIDENT OFFICE

IN THE MATTER OF:

Wedgewood Village Pharmacy, LLC — DEA Application# W15007898E
Wedgewood Animal Wellness, LLC — DEA Application# W17088272E
405 Heron Drive
Swedesboro, NJ 08085

MEMORANDUM OF AGREEMENT

On or about 2/5/2015, the Drug Enforcement Administration (DEA) received an application for controlled substance registration (DEA control number W15007898E) from Wedgewood Village Pharmacy, LLC 405 Heron Drive, Swedesboro, NJ 08085. On or about 8/18/2017, DEA received another application for controlled substance registration (DEA control number W17088272E) from Wedgewood Animal Wellness LLC, 405 Heron Drive, Swedesboro, NJ 08085.

This Memorandum of Agreement (MOA) between the DEA and Wedgewood Village Pharmacy LLC establishes terms and conditions under which the DEA will issue a registration to Wedgewood Village Pharmacy LLC as a Manufacturer to handle Schedules III through V controlled substances subject to the terms set forth below in this Memorandum of Agreement. This MOA applies only to the manufacturing registration to be issued to Wedgewood Village Pharmacy LLC.

Wedgewood agrees to enter into this MOA with the DEA for a period of five (5) years from the date the MOA is signed and fully executed. The MOA shall be considered fully executed when all parties to the MOA have signed and dated the MOA.

Wedgewood agrees to not manufacture or distribute any controlled substances for human use under the DEA issued manufacturing registration.

Wedgewood agrees to contact DEA immediately if there is any change to their business practice of selling controlled substances for animal use only pursuant to their DEA issued manufacturing registration.

Wedgewood shall abide by and obey all federal, state, and local laws and requirements relating to controlled substances.

Wedgewood agrees to immediately notify DEA if there is any change of status in its State of New Jersey license and/or State Controlled Dangerous Substance license, including any actions filed against these licenses.

Wedgewood agrees to allow DEA to conduct onsite inspections, including inspections of its controlled substances records, without prior notice pursuant to a Notice of Inspection of Controlled Premises and without requiring DEA to obtain an Administrative Inspection Warrant, Search Warrant, or other means of entry

Wedgewood agrees that this MOA constitutes the entire agreement between Wedgewood and DEA, and may only be modified or amended by a subsequent document executed in the same manner by both parties in writing.

Wedgewood shall report any professional, civil, or criminal action concerning controlled substances that is pending or taken against the firm by any state, federal, or professional agency or governing body to DEA, Camden Resident Office.

Wedgewood shall maintain a complete and accurate record of all controlled substances manufactured or distributed pursuant to this manufacturing registration.

Wedgewood agrees by executing this MOA, it waives judicial review, and will not challenge or contest the validity of any terms or conditions of this agreement.

The parties further agree that should Wedgewood violate any terms or conditions of this agreement, such violation may constitute grounds for the revocation, or the revocation and immediate suspension, of Wedgewood's DEA manufacturing registration. Nothing in this MOA shall preclude Wedgewood from contesting any subsequent Order to Show Cause, or Order to Show Cause and Immediate Suspension, of its DEA manufacturing registration as permitted under the Controlled Substances Act and the Administrative Procedure Act. Nothing in this MOA shall be construed as a waiver on the part of DEA to utilize any violations, past or subsequent, as grounds for revocation of Wedgewood's DEA manufacturing registration, either by themselves or in conjunction with other grounds, in the event that future DEA administrative proceedings become necessary. Furthermore, DEA is not precluded from introducing this MOA at any subsequent DEA administrative proceeding.

DEA agrees to promptly approve Wedgewood's application for a manufacturing registration, control# W15007898E, upon the signing of this MOA by both parties.

The parties agree that Wedgewood's application, control# W17088272E is withdrawn effective the execution of this agreement.

The responsible Wedgewood official below acknowledges and states that s/he has read the foregoing and understands and agrees with the contents herein and that s/he has signed this MOA.

The parties enter into this MOA with the understanding that the Drug Enforcement Administration and Wedgewood Village Pharmacy LLC will abide by its contents in good faith.

Wedgewood Village Pharmacy, LLC — Date: 7/20/18

FOR THE DRUG ENFORCEMENT ADMINISTRATION

Nancy Coffey — Date
Diversion Program Manager
New Jersey Division

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2016 73882
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2016 73882	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7938

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2018 82132
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2018 82132	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7945

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2018 82132
NRP 1826

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2018 82132 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2016 73882
NSC 100970

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2016 73882 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NSC 100970
CITATION AND FINE CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4685

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

Jennifer Sevilla

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NRP 1826
CITATION AND FINE CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4678

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

Jennifer Sevilla

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 90874
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2020 90874

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, June 17, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9670

I declare under penalty of perjury that the forgoing is true and correct.

Executed on June 17, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2020 90874	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

CITATION ISSUED ON: June 17, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation and Fine, Order of Abatement ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation and indicates, within the Order of Abatement, information and/or material to be submitted to the Board.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- July 17, 2021: Unless the Citation is contested, Proof of Abatement and payment of fine(s) must be received by the Board, or as directed in Order of Abatement at the bottom of your citation.
- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), timely payment of any fine(s) and the submission of Proof of Abatement shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations title 16 section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2020 89042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, April 28, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Order of Abatement, Proof of Abatement, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9687

I declare under penalty of perjury that the forgoing is true and correct.

Executed on April 28, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

Citation Number	Name, License No
CI 2020 89042	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**	**$2,500.00**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

In addition to the issued citation, Wedgewood Village Pharmacy shall provide (1) payment in the amount of $2,500.00 and (2) justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued.

If Wedgewood Village Pharmacy fails to provide justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued, this shall constitute a ground for revocation or suspension of your license, permit, or registration.

CITATION ISSUED ON: June 17, 2021	TOTAL AMOUNT OF FINE(S): $2,500.00

PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: July 17, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 29, 2021

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

This is in response to the administrative fine and proof of abatement provided to the board for the above referenced citation. The payment and documentation have been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Enforcement Manager, Susan Cappello at (916) 518-3008.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 21, 2024

CERTIFIED MAIL

Wedgewood Village Pharmacy
Attn: Marcy Ann Bliss, CEO
405 Heron Drive
Swedesboro, NJ 08085

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy LLC, dba Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

Dear Ms. Bliss:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to pages 5 – 6 of the document.

Effective at 5:00 p.m. on March 22, 2024, Nonresident Pharmacy Permit Nos. NRP 2526 & NRP 1826 and Nonresident Sterile Compounding Permit Nos. NSC 101673 & NSC 100970 issued to Wedgewood Village Pharmacy, shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Kristina T. Jarvis, DAG
Derek Shaffer, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
Wedgewood Village Pharmacy Attn: Marcy Ann Bliss, CEO 405 Heron Drive Swedesboro, NJ 08085	9589 0710 5270 0843 9755 17
Quinn Emanuel Urquhart & Sullivan, LLP Attn: Derek Shaffer, Esq. 1300 I St., NW., Ste. 900 Washington, D.C. 20005	9589 0710 5270 0843 9755 24

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 21, 2024, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 21, 2024, at Sacramento, California

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

WEDGEWOOD VILLAGE PHARMACY LLC; dba
WEDGEWOOD VILLAGE PHARMACY;
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 2526,
Nonresident Sterile Compounding Permit No. NSC 101673; and

WEDGEWOOD VILLAGE PHARMACY LLC;
WEDGEWOOD VILLAGE PHARMACY
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondents

Agency Case No. 7286

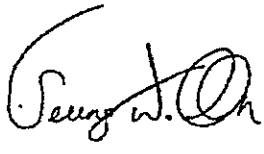
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 22, 2024.

It is so ORDERED on February 21, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC; 405 Heron Drive Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526, Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; ALISON LYNCH, PIC; 405 Heron Drive, Suite 200 Swedesboro, NJ 08085**	Case No. 7286 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970

Respondents.

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Kristina T. Jarvis, Deputy Attorney General.

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge (Respondent Original Licensee). On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

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4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Succcssor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

6. Respondent is represented in this proceeding by attorney Derek Shaffer whose address is: 1300 I Street NW, Suite 900, Washington D.C. 20005.

JURISDICTION

7. Accusation No. 7286 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on April 27, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. On July 26, 2023, Complainant filed a First Amended Accusation. A copy of First Amended Accusation No. 7286 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7286. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

9. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

10. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

11. NRP 1826 and NSC 101673 have been cancelled, and the Board confirms that there are no pending allegations or investigations against these licenses, and therefore no future administrative or disciplinary action is contemplated.

CULPABILITY

12. Respondent understands and agrees that the charges and allegations in Accusation No. 7286, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits.

13. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

14. Respondent agrees that its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

15. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action

between the parties, and the Board shall not be disqualified from further action by having considered this matter.

16. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

17. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

18. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970, Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673 issued to Respondents shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7286, attached as exhibit A.

Cost Recovery. No later than 1 YEAR from the effective date of the Decision, Respondent shall pay $11,054.75 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Nonresident Pharmacy Permit NRP 2526, or Nonresident Sterile Compounding Permit No. NSC 101673 until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 7286, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Derek Shaffer. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/2/2024 | 1:23 PM PST

WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, and TW DIAMONDBACK HOLDINGS CORPORATION, dba WEDGEWOOD VILLAGE PHARMACY LLC;

DocuSigned by:
By: MARCY ANN BLISS Marcy Ann Bliss
253A168EA289425...

Title: CEO
Respondent

I have read and fully discussed with Respondent Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation, dba Wedgewood Village Pharmacy LLC, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 1/4/2024 | 7:34 AM PST

DocuSigned by:
Derek Shaffer
DEREK SHAFFER
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: January 11, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

SA2022301557

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 7286
WEDGEWOOD VILLAGE PHARMACY LLC; **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **MARCY ANN BLISS, CEO;** **JOSEPH COSTA, COO;** **ALISON LYNCH, PIC;** **405 Heron Drive** **Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526,** **Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC;** **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **LUDMILLA MALMBERG, Chairman;** **MARCH ANN BLISS, CEO;** **JOCELYN ROSE STANLEY, Secretary;** **THOMAS J. FORMOLO, Secretary;**	**ACCUSATION**

EDWARD MICHAEL LHEE, Secretary;
ALISON LYNCH, PIC;
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondent.

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Chairman, Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge. On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Ludmilla Malmberg, Chairman,Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Original Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

JURISDICTION

6. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4011 of the Code states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

8. Section 4300 of the Code states in pertinent part:

(a) Every license issued may be suspended or revoked.

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

9. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not

deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

10. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

11. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(c) Gross negligence.

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency....

REGULATORY PROVISIONS

12. California Code of Regulations, title 16, (Regulations) section 1735.2 states in pertinent part:

...

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

...

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

...

(*l*) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

13. Regulations section 1735.3 states in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

...

(2) A compounding log consisting of a single document containing all of the following:

...

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply....

COST RECOVERY

14. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG PREPARATIONS

15. Tacrolimus Ophthalmic Suspension is an eye drop generally prescribed to dogs to treat dry eyes, particularly when caused by low tear production or tears of poor quality. It is a dangerous drug pursuant to Code section 4022.

16. Protirelin is an injectable drug product generally prescribed for horses as a thyrotropin-releasing hormone in order to test for certain metabolic disorders or illnesses. It is a dangerous drug pursuant to Code section 4022.

17. Cyclosporine in MCT oil solution is an eye drop generally prescribed to dogs. It is used to decrease inflammation in the eye and tear glands and increase tear production. It is a dangerous drug pursuant to Code section 4022.

18. Edetate Disodium (EDTA) is a chelating agent generally prescribed to treat corneal ulcers in dogs, cats, and horses. It is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

19. Respondents own and operate a nonresident pharmacy which also possesses a nonresident sterile compounding pharmacy permit, and is located in the State of New Jersey.

20. On or about April 1, 2021, due to a change in the ownership structure of certain parent corporations that own the corporations that own Respondent Original Licensee, successor licensees, both a nonresident pharmacy permit and a nonresident sterile compounding pharmacy permit, were issued to the same immediate ownership structure. Nearly all of the immediate owners and officers of Respondent Original Licensee remained with Respondent Successor Licensee. The conduct set forth in this accusation came to the attention of the Board due to the change of ownership inspection that is required by pharmacy law. Therefore, all of the actions were taken on dates on which Respondent Original Licensee was the owner and operator of the pharmacy. However, since the immediate ownership structure did not change, the owners and operators of Respondent Successor Licensee are responsible for the actions of Respondent Original Licensee.

21. Respondents specialize in veterinary compounding.

22. On January 1, 2017, the Board's sterile compounding regulations became effective.

23. In 2017, Board inspector S.P. issued a written warning to Respondents due to Respondents issuing many of its drug preparations extended beyond use dates (BUDs) without the appropriate data to support those BUDs.

24. In 2018, and again in 2020, during inspections of Respondents facility, Board inspector S.P. discussed with Respondents the documentation Respondents needed to provide, obtain, or test for, in order determine and assign extended BUDs and noted that Respondents had not obtained, tested for, or provided this documentation such that the extended BUDs were still inappropriate.

25. After the 2020 inspection, the Board issued a citation to Respondents for providing 120-day extended BUDs without having the tests and studies required to support the extended BUDs.

///

26. On and between approximately March 17, 2021, and May 28, 2021, Board Inspector M.V. conducted a change of ownership inspection regarding Respondents as discussed in additional depth, above. Due to the COVID-19 pandemic, the inspection was conducted remotely via records review. The investigation report is dated March 1, 2022 (March 1, 2022 Inspection Report).

27. On or about March 19, 2021, Board Inspector M.V. requested five specific compounding logs for review, including certificates of analyses, end-product release testing, documentation supporting any extended BUDs assigned to preparations, sample labels, and training records for Respondents' compounding pharmacist and compounding pharmacy technician. M.V.'s review of just these five compounding logs lead to the causes for discipline set forth below.

FIRST CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Dates)

28. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations 1735.2, subdivision (i). The circumstances are as follows:

A. On or about July 1, 2020, Respondents compounded 623 bottles of Tacrolimus 0.03% ophthalmic aqueous suspensions and gave an extended BUD of 160 days. Respondents only had data to support a 45-day BUD for this drug product.

B. On or about November 27, 2020, Respondents compounded 581 bottles of Cyclosporine 2% in MCT oil ophthalmic solutions and gave an extended BUD of 180 days. Respondents only had data to support a 45-day BUD for this drug product.

C. On or about February 8, 2021, Respondents compounded 353 vials of Protirelin Acetate 1mg/ml injectable solution and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for this product.

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D. On or about March 10, 2020, Respondents compounded 53 bottles (15mL) of Edetate Disodium and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for the product.

SECOND CAUSE FOR DISCIPLINE

(Incomplete Compounding Records)

29. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations section 1735.3, subdivision (a)(2). The circumstances are that Respondents' compounding logs reviewed by Board Inspector M.V. failed to list the manufacturers of the drug components Respondents used for compounding.

THIRD CAUSE FOR DISCIPLINE

(Gross Negligence)

30. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (c), in that Respondents committed acts constituting gross negligence when Respondents assigned extended BUDs without having the required data to support those BUDs.

FOURTH CAUSE FOR DISCIPLINE

(Knowingly Making or Signing a False Document)

31. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents knowingly made or signed false documents when Respondents assigned extended BUDs without having the required data to support those BUDs.

FIFTH CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

32. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption when Respondents continued to assign extended

BUDs and ship the compounded drugs to patients without having the required data to support those BUDs.

DISCIPLINARY CONSIDERATIONS

33. On or about June 17, 2021, Citation number CI 2020 90874 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation did not order a fine, it was not appealed, and it is final.

34. On or about June 17, 2021, Citation number CI 2020 89042 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation ordered a $2,500 fine, and required proof of abatement regarding justification for assigning extended BUDs for antibacterial eye ointment. The citation was not appealed and is final.

35. On or about December 5, 2018, Citation number Cl 2018 82132 was issued to Respondent Original Licensee's Nonresident Pharmacy permit f or violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

36. On or about December 5, 2018, Citation number Cl 2016 73882 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

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37. On or about October 13, 2017, Citation number CI 2017 77042 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Code section 4059.5, subdivision (b), for selling prescription items to individual. S.G. who was not authorized to purchase these items. S.G. represented himself as a physician and Respondent Original Licensee failed to note the discrepancy between S.G.'s address and the address of the physician he was impersonating. The citation ordered a $1,000 fine, it was not appealed, and it is final.

OTHER MATTERS

38. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 2526 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 101673 issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC then Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, and if Ludmilla Malmberg, Marcy Ann Bliss, Joseph Costa, and Alison Lynch are proven to have knowledge of or have participated in the conduct, then each shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Nonresident Pharmacy Permit number NRP 1826, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

2. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 100970, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

///

3. Revoking or suspending Nonresident Pharmacy Permit number NRP 2526, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

4. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 101673, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

5. Prohibiting Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Ludmilla Malmberg from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

7. Prohibiting Marcy Ann Bliss from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

8. Prohibiting Joseph Costa from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

9. Prohibiting Alison Lynch from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

10. Ordering Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Marcy Ann Bliss, and Joseph Costa to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

///

11. Taking such other and further action as deemed necessary and proper.

DATED: 4/5/2023

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2023.04.15 07:02:07 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2022301557
Wedgewood Acc.docx

GOVERNMENT CODE - GOV

TITLE 2. GOVERNMENT OF THE STATE OF CALIFORNIA [8000 - 22980] *(Title 2 enacted by Stats. 1943, Ch. 134.)*

DIVISION 3. EXECUTIVE DEPARTMENT [11000 - 15986] *(Division 3 added by Stats. 1945, Ch. 111.)*

PART 1. STATE DEPARTMENTS AND AGENCIES [11000 - 11898] *(Part 1 added by Stats. 1945, Ch. 111.)*

CHAPTER 5. Administrative Adjudication: Formal Hearing [11500 - 11529] *(Heading of Chapter 5 amended by Stats. 1995, Ch. 938, Sec. 22.)*

11521. (a) The agency itself may order a reconsideration of all or part of the case on its own motion or on petition of any party. The agency shall notify a petitioner of the time limits for petitioning for reconsideration. The power to order a reconsideration shall expire 30 days after the delivery or mailing of a decision to a respondent, or on the date set by the agency itself as the effective date of the decision if that date occurs prior to the expiration of the 30-day period or at the termination of a stay of not to exceed 30 days which the agency may grant for the purpose of filing an application for reconsideration. If additional time is needed to evaluate a petition for reconsideration filed prior to the expiration of any of the applicable periods, an agency may grant a stay of that expiration for no more than 10 days, solely for the purpose of considering the petition. If no action is taken on a petition within the time allowed for ordering reconsideration, the petition shall be deemed denied.

(b) The case may be reconsidered by the agency itself on all the pertinent parts of the record and such additional evidence and argument as may be permitted, or may be assigned to an administrative law judge. A reconsideration assigned to an administrative law judge shall be subject to the procedure provided in Section 11517. If oral evidence is introduced before the agency itself, no agency member may vote unless he or she heard the evidence.

(Amended by Stats. 2004, Ch. 865, Sec. 34. Effective January 1, 2005.)

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☒ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 002236	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Veterinary compounding	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FD7902972 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Veterinary

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: WEDGEWOOD PHARMACY LLC

Physical Address: 7631 EAST INDIAN SCHOOL ROAD, SUITE 105

City: SCOTTSDALE State: AZ Zip: 85251

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-331-8272 Toll Free # (NAC 639.708, NRS 639.23286): 800-331-8272

Fax: 866-646-2235 Contact Email: LICENSING@WEDGEWOODPHARMACY.COM

Website: WWW.WEDGEWOODPHARMACY.COM

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): CHRIS PUCILLO

Supervising/Managing Pharmacist NV Pharmacist Registration # (~~if applicable~~): ~~N/A~~ Ali Oden 23861

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Ali Odeh	NV Pharmacist Registration #: 23861
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DELAWARE

Parent Company (if any): WEDGEWOOD HOLDINGS INC

Corporation/Organization Name: WEDGEWOOD PHARMACY LLC

Mailing Address: 405 HERON DRIVE, SUITE 200

City: SWEDESBORO State: NJ Zip: 08085

Telephone: 800-331-8272 Email: LICENSING@WEDGEWOODPHARMACY.COM

Contact Person Name: JOE COSTA

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President/COO (title) for Wedgewood Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Joseph Costa

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/15/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Costa, President/COO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4/15/2024
Date

Board Use Only	Date Received: 4/17/24	Amount: $500 - Check 55858

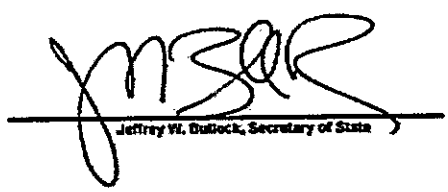
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "WEDGEWOOD VILLAGE PHARMACY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF MARCH, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





5944344 8300

SR# 20241174280

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203115229

Date: 03-26-24

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

DEMOGRAPHICS

AZ permit# :	AZ Permit Exp.Date :	Business Name :
Y007637	10/31/2023	Wedgewood Village Pharmacy, LLC
Address :		
7631 E. Indian School Rd., Suite 105		
Zip :	City :	State :
85251	Scottsdale	AZ
Phone :	Fax :	Email :
(480) 946-2223	(480) 946-2235	andrew.warther@wedgewoodpharmacy.com
Inspection Date :	PIC :	Pic License Exp Date :
11/09/2022	Andrew Warther	10/31/2023
DEA # :	DEA # Exp. date :	Inspection Reviewed With :
FD7902972	05/31/2024	Andrew Warther
Reviewers License# :	Inspection type :	
S020613	Routine	
Inspection Conducted By :		
Dennis Waggoner		

Facility Data

# Rxs/Week	RPh Hours/Week	# Rxs/Hours
12000	1400	8.571428571428571

PERMITS

1	Arizona	◉S ○N/I ○V ○N/A	ARS § 32-1933(A); R4-23-606(A)
2	DEA	◉S ○N/I ○V ○N/A	ARS § 36-2522(A)(2); 21 CFR 1301.35(c)
3	Suppliers	◉S ○N/I ○V ○N/A	ARS § 32-1929; R4-23-601(A); R4-23-604(A); R4-23-605(A); R4-23-607(A)

LICENSES

1	Pharmacists	◉S ○N/I ○V ○N/A	ARS § 32-1925(A); R4-23-201(A)
2	Interns / Graduate interns	◉S ○N/I ○V ○N/A	ARS § 32-1923(B); R4-23-301(G)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

3	Technicians / Trainees	◉S ○N/I ○V ○N/A	ARS § 32-1925(A); R4-23-1101(A); R4-23-1102(D); R4-23-1103(B)(2)
4	Current renewal licenses maintained	◉S ○N/I ○V ○N/A	ARS § 32-1933(B)

PHARMACY

1	Drug storage and security	◉S ○N/I ○V ○N/A	R4-23-609(G)(H)
2	Personnel and security procedures	◉S ○N/I ○V ○N/A	R4-23-610
3	Facilities	◉S ○N/I ○V ○N/A	R4-23-611(A)
4	Drug supply	◉S ○N/I ○V ○N/A	R4-23-611(B)
5	Quarantine expired drugs	◉S ○N/I ○V ○N/A	R4-23-611(B)(4)
6	Equipment	◉S ○N/I ○V ○N/A	R4-23-612
7	Policies and procedures	◉S ○N/I ○V ○N/A	R4-23-610(A); R4-23-611(B)

TECHNICIANS

1	Training program	◉S ○N/I ○V ○N/A	R4-23-1105(B)(D)
2	Training program - compounds	◉S ○N/I ○V ○N/A	R4-23-1105(C)
3	Activities - trainees	◉S ○N/I ○V ○N/A	R4-23-1104(A)
4	Activities - technicians	◉S ○N/I ○V ○N/A	R4-23-1104(A)(B)
5	Policies and procedures Suggest documentation of follow up for any failed items noted in technician annual competency assessment.	◉S ○N/I ○V ○N/A	R4-23-1104(F)(G)

COUNSELING

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

1	Documentation Reminder for pharmacist to initial all entries.	◉S ○N/I ○V ○N/A	R4-23-402(G)(H)
2	Oral consultation	◉S ○N/I ○V ○N/A	R4-23-402(C)(D)(E)
3	Written information	◉S ○N/I ○V ○N/A	R4-23-402(C)(I)

PRESCRIPTION AUDIT

1	Prescription files	◉S ○N/I ○V ○N/A	ARS § 32-1964; ARS § 36-2525(C)(1)(2)
2	Prescription label	◉S ○N/I ○V ○N/A	ARS § 32-1968(D); ARS § 36-2525(L)
3	CII prescriptions	◉S ○N/I ○V ○N/A	ARS § 32-1968; 36-2525(A) to (G); R4-23-407(A)
4	CIII - CV prescriptions	◉S ○N/I ○V ○N/A	ARS § 32-1968; 36-2525(A)(C)(2)(H)(I); R4-23-407(A)
5	Non-controlled prescriptions	◉S ○N/I ○V ○N/A	ARS § 32-1968; R4-23-407(A)
6	Transfers	◉S ○N/I ○V ○N/A	R4-23-407(D)
7	Telephone	◉S ○N/I ○V ○N/A	ARS § 32-1968(A)(5); R4-23-402(A)(1)(2)
8	Refill authorizations	○S ○N/I ○V ◉N/A	ARS § 32-1968(A)(6); R4-23-402(A)(13); R4-23-407(E)(5)
9	Facsimile	○S ○N/I ○V ◉N/A	R4-23-407(E)
10	Electronically transmitted	○S ○N/I ○V ◉N/A	R4-23-407(F); R4-23-408(H)
11	Patient information	◉S ○N/I ○V ○N/A	R4-23-402(A)(3)(4)
12	Allergies / medical conditions	◉S ○N/I ○V ○N/A	R4-23-402(A)(3)(b)
13	Brand / generic	◉S ○N/I ○V ○N/A	ARS § 32-1963 01

14	Foreign prescriptions	◉S ○N/I ○V ○N/A	ARS § 32-1969
15	Prescription blank advertising prohibited	○S ○N/I ○V ◉N/A	R4-23-404(B); ARS § 32-1901.01(B)(25)
16	Prescription audit numbers C2: 6285000-629999, C3-5: 6306000-6306999, Random non-controlled imaged prescriptions reviewed.		

COMPUTER REQUIREMENTS

1	Security	◉S ○N/I ○V ○N/A	R4-23-408(F)
2	Log books / printout	◉S ○N/I ○V ○N/A	R4-23-408(C)(4)
3	Reports Reminder to have capability to generate a single drug usage report with the required elements.	◉S ○N/I ○V ○N/A	R4-23-408(B)(5)(6)
4	Policies and procedures	○S ○N/I ○V ◉N/A	R4-23-408(A)

IMMUNIZATIONS

1	Certification	○S ○N/I ○V ◉N/A	ARS § 32-1974(D)(K), R4-23-411(A)
2	Recordkeeping	○S ○N/I ○V ◉N/A	ARS § 32-1974(F)(3); R4-23-411(F)(I)
3	Reporting requirements	○S ○N/I ○V ◉N/A	ARS § 32-1974(F); R4-23-411(F)(2)
4	Current certificate maintained	○S ○N/I ○V ◉N/A	R4-23-411(C)(2)
5	Administration without a prescription	○S ○N/I ○V ◉N/A	ARS § 32-1974(A)(B); R4-23-411(A)
6	Prescription only administration	○S ○N/I ○V ◉N/A	ARS § 32-1974(C)(I); R4-23-411(A)(4); (B); (I)

MECHANICAL STORAGE / COUNTING DEVICES

1	Cell identification	○S ○N/I ○V ◉N/A	R4-23-615(A)(1)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

2	Paper / electronic log	○S ○N/I ○V ◉N/A	R4-23-615(A)(2)(3)
3	Training	○S ○N/I ○V ◉N/A	R4-23-615(C)(1)(D)
4	Maintenance	○S ○N/I ○V ◉N/A	R4-23-615(C)(2)(D)
5	Accuracy validation testing	○S ○N/I ○V ◉N/A	R4-23-615(C)(3)(D)
6	Return by approval only	○S ○N/I ○V ◉N/A	R4-23-615(B)(G)
7	Policies and procedures	○S ○N/I ○V ◉N/A	R4-23-615(E)

MECHANICAL COUNTING DEVICES

1	Training	◉S ○N/I ○V ○N/A	R4-23-616(A)(1)(B)
2	Maintenance	◉S ○N/I ○V ○N/A	R4-23-616(A)(2)(B)
3	Accuracy validation testing Reminder to document for each day used.	◉S ○N/I ○V ○N/A	R4-23-616(A)(3)(B)
4	Policies and procedures	◉S ○N/I ○V ○N/A	R4-23-616(C)

CONTROLLED SUBSTANCE RECORDS

1	CIIs purchase / sale / disposal	◉S ○N/I ○V ○N/A	ARS § 36-2523(A); ARS § 36-2524; R4-23-601(D);R4-23-1003(A)(4)(B)
2	CIII - CVs purchase / sale / disposal	◉S ○N/I ○V ○N/A	ARS § 36-2523(A); R4-23-601(D); R4-23-612(11); R4-23-1003(A)(4)
3	Inventory Add column for Total Packages.	◉S ○N/I ○V ○N/A	ARS § 36-2523(B); R4-23-1003
4	Audit Hydrocodone/Homatrapine shortage likely a result of using 480mL/bottle vs labeled 473mL/bottle on inventory document.	◉S ○N/I ○V ○N/A	ARS § 36-2523

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

5	DEA 106 Theft/Loss reporting	◉S ○N/I ○V ○N/A	R4-23-1003(A)(2); 21 CFR 1301.76(b)

MISCELLANEOUS

1	Badges - name / title	◉S ○N/I ○V ○N/A	R4-23-402(K); R4-23-671(B)(4); R4-23-1104(E)
2	Sales of drugs to practitioners	◉S ○N/I ○V ○N/A	ARS § 32-1981(7)(d); R4-23-601(D); R4-23-1003(A)(4)
3	Schedule V register	○S ○N/I ○V ◉N/A	ARS § 36-2525(J)
4	Delivery	◉S ○N/I ○V ○N/A	ARS § 32-1901.01(B)(23); R4-23-402(I)
5	CQA training / Policies and procedures	◉S ○N/I ○V ○N/A	ARS § 32-1973; R4-23-620
6	Non-controlled substances purchase / sale / disposal	◉S ○N/I ○V ○N/A	R4-23-601(D)
7	Dextromethorphan sales restrictions	○S ○N/I ○V ◉N/A	ARS 32-1978
8	Federal medication guides	○S ○N/I ○V ◉N/A	21 CFR part 208
9	Pharmacy to pharmacy transfer of drugs (intracompany) Reminder to add the license/permit number of each pharmacy to the invoice.	◉S ○N/I ○V ○N/A	R4-23-601(D); R4-23-1003(A)(4)

METHAMPHETAMINE PRECURSORS

1	Storage	○S ○N/I ○V ◉N/A	ARS § 32-1977(B)
2	Documentation	○S ○N/I ○V ◉N/A	ARS § 32-1977(C); 21 CFR 1314
3	Self-certification	○S ○N/I ○V ◉N/A	21 CFR 1314.35; 21 CFR 1314.40

SHARED SERVICES

1	Current resident / nonresident permit	◉S ○N/I ○V ○N/A	R4-23-621(A)
2	Same owner / written contract / common electronic file	◉S ○N/I ○V ○N/A	R4-23-621(B)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

3	Notification to patients	◉S ○N/I ○V ○N/A	R4-23-621(C)
4	Maintain manual / electronic records	◉S ○N/I ○V ○N/A	R4-23-621(D)
5	Work outside pharmacy	◉S ○N/I ○V ○N/A	R4-23-621(F)
6	Policies and procedures Reminder to add the permit number of the NJ site to the SOP.	◉S ○N/I ○V ○N/A	R4-23-621(E)

COMPOUNDING PRACTICES (GENERAL)

1	Documentation product compounded	◉S ○N/I ○V ○N/A	R4-23-410(C)(1)(e); R4-23-410(I)(K)
2	Patient label	◉S ○N/I ○V ○N/A	R4-23-410(I)(4)
3	Beyond-use dates	◉S ○N/I ○V ○N/A	R4-23-410(I)(4)(b); R4-23-410(B)(3)(d)
4	Equipment	◉S ○N/I ○V ○N/A	R4-23-410(F)(G)
5	Product produced in excess	◉S ○N/I ○V ○N/A	R4-23-410(B)(2); R4-23-410(J)
6	Component removed from original container	◉S ○N/I ○V ○N/A	R4-23-410(I)(6)
7	Compounds for medical practitioners Specific language required for container label: "Not for dispensing", and "For office or hospital administration only".	○S ◉N/I ○V ○N/A	R4-23-410(B)(3); R4-23-601(D); R4-23-1003(A)(4)
8	Patient written list	◉S ○N/I ○V ○N/A	R4-23-410(I)(5)
9	Protective apparel	◉S ○N/I ○V ○N/A	R4-23-410(C)(2)(c)
10	Facility	◉S ○N/I ○V ○N/A	R4-23-410(E)
11	Components for compounding/storage	◉S ○N/I ○V ○N/A	R4-23-410(B)(H)
12	Policies and procedures	◉S ○N/I ○V ○N/A	R4-23-410(D)(G)(H)(I)(K)

STERILE COMPOUNDING

1	Compounding area Hazardous sterile compounding area no longer in use.	◉S ○N/I ○V ○N/A R4-23-670(A)(E)(F)
2	Equipment	◉S ○N/I ○V ○N/A R4-23-670(B)
3	Sterile product reference	◉S ○N/I ○V ○N/A R4-23-670(B)(6)
4	Certification hood / environment	◉S ○N/I ○V ○N/A R4-23-670(D)(14)(g)
5	Documentation routine cleaning / maintenance	◉S ○N/I ○V ○N/A R4-23-670(D)(14)(g)
6	Personnel protective clothing	◉S ○N/I ○V ○N/A R4-23-670(E)(3)(F)(2)
7	Annual / semi-annual media fill tests	◉S ○N/I ○V ○N/A R4-23-670(E)(4)(F)(3)
8	Documentation of product compounded	◉S ○N/I ○V ○N/A R4-23-410(C)(1)(e); R4-23-410(I)(K)
9	Beyond-use dates	◉S ○N/I ○V ○N/A R4-23-670(D)(14)(d); R4-23-410(B)(3)(d)
10	Process / product validation testing	◉S ○N/I ○V ○N/A R4-23-670(D)(14)(f)
11	Policies and procedures	◉S ○N/I ○V ○N/A R4-23-670(C)(D)

AUDIT

Date Of Inventory : 05/01/2022

Inventory Taken : Open

Date Of Audit : 11/09/2022

Name & Strength of Drug	Initial Inventory	Total Purchased	Total Accounted For	Closing Inventory	Sales (Rx & log)	Total Can Account for	Difference	Percentage
Hydrocodone/Homatropine 5/1.5 syrup (mL)	12299	87978	100277	34454	65416.5	99870.5	-406.5	-0.41
Diazepam 5mg/mL 10mL vial	25	20	45	0	45	45	0	0.00
Tramadol 50mg tab	2517	2000	4517	2006	2516	4522	5	0.11

NOTES

Hours of operation: Mo-Fr 5:00A-10:00P, Lobby 9:00A-6:00P, Sa 6:30A-4:00P, Lobby 9:00A-3:00P.

Handouts: 2020/2021 Statute/Rule Changes summary, ARS 32-1926 reminder, DEA Form 106 Reporting reminder, AzBOP Newsletter October 2022, Continuing Education Audit information, AzBOP Scam Alert, FDA advisory on insulin pen packaging and dispensing, DEA reminder on manual signature for prescribers, Single Ingredient Ephedrine Products

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/08/2023
Receipt Number: 2023154690
Receipt Amount $: 480.00

Pharmacy - Independent

Compounding – Non-Sterile,Compounding – Sterile,Mail Order,Veterinarian

	PERMIT NO	**EXPIRES**
	Y007637	**10/31/2025**
Issued to :	Wedgewood Village Pharmacy, LLC Wedgewood Village Pharmacy, LLC 7631 E. INDIAN SCHOOL RD., SUITE 105 SCOTTSDALE, AZ 85251	Wedgewood Village Pharmacy, LLC 7631 E. INDIAN SCHOOL RD., SUITE 105 SCOTTSDALE, AZ 85251

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF
PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Wedgewood Village Pharmacy, LLC
LICENSE NUMBER : Y007637
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Wedgewood Village Pharmacy, LLC
Address :	7631 E. Indian School Rd., Suite 105 Scottsdale AZ 85251
Registration No :	Y007637
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	04/30/2018
Expiration Date :	10/31/2025
Status :	OPEN
Discipline :	No

Kam Gandhi

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 04/15/2024

Corporate Information
Wedgewood Pharmacy LLC
Wedgewood Connect LLC

Officers:

President:	Joseph Costa
CFO & Treasurer	Maria Kraus
Secretary	Marcy Bliss

Parent Companies:

Wedgewood Holdings Inc. (100% owner of Wedgewood Pharmacy LLC)
Specialty Pharma III Inc. (100% owner of Wedgewood Holdco Inc)
Specialty Pharma II Inc. (100% owner of Specialty Pharma III Inc.)
Specialty Pharma I Inc. (100% owner of Specialty Pharma II Inc.)
Specialty Pharma Holdings LP (100% owner of Specialty Pharma I Inc.)

Address:

405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Officers:

President & COO:	Joseph Costa
CFO:	Maria Kraus
CEO & Sec.:	Marcy Bliss

Directors:

Marcy Bliss
Sofia Gerard
Dennis Maloney
Kevin Vasquez
David Kamenetzky
Peter Berweger

Shareholders:

There are no individual shareholders in Wedgewood Connect/Village Pharmacy as both entities are member managed limited liability companies.

All shares in Wedgewood Holdings Inc. are held by Specialty Pharma III Inc.

Marcy Bliss, Maria Kraus and Joseph Costa have served as officers at the following pharmacy locations:

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
7631 E. Indian School Road, Suite 105
Scottsdale, AZ 85251

ZooPharm LLC (now closed)
3131 Grand Ave., Unit C, Laramie, WY 82070

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Wedgewood Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable) PH02236

Physical Address 7631 East Indian School Road Suite 105

City Scottsdale State AZ Zip 85251

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-331-8272 Website _____

Licensing Company Email licensing@wedgewoodpharmacy.com

Section 2: Personal Information

First Ali Middle Mohammad Last Odeh

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] North Almar

City Mesa State AZ Zip 85213

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University		08/07-06/10	
Address	**City**	**State**	**Zip**
19555 N 59th Ave	Glendale	AZ	85308
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Paradise Valley Community College			
Address	**City**	**State**	**Zip**
18401 N 32nd St	Phoenix	AZ	85032
Diploma/Degree obtained, if any			
AA/AS			

School Name		From - To (MM/YY – MM/YY)	
Horizon High School		08/01-06/05	
Address	**City**	**State**	**Zip**
5601 E Greenway Rd	Scottsdale	AZ	85254
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/17 - 04/24	[redacted] North Almar	Mesa	AZ	85213
1/15 - 1/17	[redacted] North 21st Avenue	Phoenix	AZ	85015
4/14 - 1/15	[redacted] East Crocus Drive	Scottsdale	AZ	85254

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Wedgewood Village Pharmacy LLC			02/13 - 04/24	
Business Address		**City**	**State**	**Zip**
7631 E Indian School Rd		Scottsdale	AZ	85251
Phone	**Title**		**Number of Employed Hours**	
800-331-8272	Pharmacist/Pharmacist Quality Manager		21280	
Description of Duties				
Staff pharmacist providing supervision of compounding and verification of orders. Manager of pharmacists.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, ALI ODEH, **certify that as the designated representative for**

WEDGEWOOD PHARMACY LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AO AO I am at least 21 years of age;
3. AO AO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AO AO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AO AO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AO AO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AO AO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

ALI, ODEH

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/11/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ALI, ODEH

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/11/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, ALI ODEH, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/11/2024

Date

Subscribed and Sworn to before me this 11th day of April, 2024.

Notary Public Signature

SARAH M HODGMAN
Notary Public - Arizona
Maricopa County
Commission # 584237
My Comm. Expires Jul 10, 2024

(Seal)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FD7902972	05-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-15-2021

WEDGEWOOD VILLAGE PHARMACY, LLC
7631 E INDIAN SCHOOL RD STE 105
SCOTTSDALE, AZ 852513607

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
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FD7902972	05-31-2024	$888

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7631 E INDIAN SCHOOL RD STE 105
SCOTTSDALE, AZ 852513607

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Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Wedgewood Pharmacy LLC

NV Pharmacy or Outsourcing facility license # (if applicable): PH02236 (current license number)

Physical Address: 7631 E Indian School Road, Suite 105

City: Scottsdale State: AZ Zip: 85024

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-331-8272 Toll Free # (NAC 639.708, NRS 639.23286): 800-331-8272

Fax: 866-646-2235 Contact Email: licensing@wedgewoodpharmacy.com

Website: www.wedgewoodpharmacy.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Ali Odeh

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23861

Name of Person with direct knowledge of compounding procedures: Ali Odeh

Email of Person with direct knowledge of compounding procedures: ali.odeh@wedgewoodpharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 800-331-8272

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

ATIPAMEZOLE BASE 25MG/ML INJ
BAM (BUTORPHANOL TARTRATE/AZAPERONE/MEDETOMIDINE HCL 27.3MG/9.1MG/10.9MG/ML) INJ
BUTORPHANOL TARTRATE 50MG/ML INJ
EDETATE DISODIUM AQUEOUS 1% OPH
KETAMINE HCl 200MG/ML INJ
MIDAZOLAM HCl 50MG/ML INJ
MK (MEDETOMIDINE HCL/KETAMINE HCL 5MG/150MG/ML) INJ
NalMed-A: (NALBUPHINE HCL/MEDETOMIDINE HCL/AZAPERONE 40MG/10MG/10MG/ML) INJ
NALTREXONE HCl 50MG/ML INJ
TRAMADOL HCL 50MG/ML INJ

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

Wedgwood Pharmacy has performed extensive stability testing on all of our compounded sterile products (CSPs). Our stability testing included forced degradation studies of the active ingredient(s), antimicrobial effectiveness testing (if applicable), sterility, endotoxin, PH, container closure integrity and subvisible particle testing.

6. What laboratory performs this additional testing?

Name: Please see attached list

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?

Visual inspection is performed on each CSP unit at completion of compounding, at batch release and prior to dispensing.

8. How often do you perform glove fingertip and medial fill testing?

Gloved fingertip (GFT) sampling is performed initially for each compounding staff member in triplicate. In addition, GFT sampling is performed on a rotating technician basis every week. Media fill testing is performed every 3 months.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

If an employee fails a glove fingertip sample or a media fill, a variance will be investigated to determine root cause. The employee may complete additional training and will be required to successfully pass their assessments as part of their qualification processes. Results of the evaluation and corrective actions, in the event of failure, are documented and maintained to provide a long term assessment of the personnel competency.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Prior to compounding, all employees must complete a sterile compounding didactic review consisting of 20 hours for pharmacists and 40 hours for technicians. USP 797 will be reviewed at least every 6 months. Employees must demonstrate knowledge and competency initially and at least every 12 months in hand hygiene, garbing, cleaning disinfection, handling and transporting CSPs, calculations, measuring, mixing, aseptic technique, achieving and maintaining sterility, proper use of equipment, documentation of compounding process, principle of HEPA airflow, use of the PEC and principles of movement of materials and personnel within the compounding area. Employees must successfully pass a garbing competency with fingertip sampling 3 times in succession initally then every 3 months thereafter. In addition, all compounding staff must successfully pass a media fill every 3 months.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Interior surfaces in the PEC are cleaned daily on days when compounding occurs, in between batches and when surface contamination in known or suspected. In addition, the PECs are cleaned weekly and monthly during our required weekly and monthly cleaning events. For daily cleanings of the PEC Decon Cycle and sterile 70% IPA are utilized. For weekly and monthly cleanings, both sterile Peridox and Hypo-Clor 0.52% are used. Both Peridox and Hypo-Chlor are sporicidal agents. The secondary engineering controls are cleaned daily, weekly and monthly on days when the sterile suite is open. For daily cleanings, sterile Decon-Cycle is used on all areas except the floor. For daily floor cleaning, sterile Cyquanol is used. Peridox and Hypo-Chlor 0.52% are used for all weekly and monthly cleanings.

12. Who performs the sterile compounding process at your facility?

Only pharmacists and technicians who are properly licensed and trained will perform compounded processes at our facility.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The Pharmacist-in-Charge is ultimately responsible and accountable for the sterile compounding at the facility and works in collaboration with the sterile compounding staff.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Compounded preparations are properly packaged to preserve quality, strength, purity, integrity and sterility. Packages should protect the compounded preparation from temperature extremes, physical damage and light (If required). Glass vials or bottles are shipped after being wrapped in bubble wrap or similar material and placed in an appropriate sized box. Temperature verification testing is performed at least twice annually to ensure that shipped packages maintain required temperature ranges. Mailed compounded preparations that require refrigeration are packaged in a cooler with ice-packs, and a temperature indicator card.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

ATIPAMEZOLE BASE 25MG/ML INJ
BAM (BUTORPHANOL TARTRATE/AZAPERONE/MEDETOMIDINE HCL 27.3MG/9.1MG/10.9MG/ML) INJ
BUTORPHANOL TARTRATE 50MG/ML INJ
EDETATE DISODIUM AQUEOUS 1% OPH
KETAMINE HCl 200MG/ML INJ
MIDAZOLAM HCl 50MG/ML INJ
MK (MEDETOMIDINE HCL/KETAMINE HCL 5MG/150MG/ML) INJ
NalMed-A: (NALBUPHINE HCL/MEDETOMIDINE HCL/AZAPERONE 40MG/10MG/10MG/ML) INJ
NALTREXONE HCl 50MG/ML INJ
TRAMADOL HCL 50MG/ML INJ

2. What sterilization methods are utilized at your facility?

This facility uses sterile filtering and autoclaving for sterilizing methods.

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:

Biological indicators are used in each autoclave cycle to verify the effectiveness of the sterilization cycle.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ali Odeh

Name of Person who Completed the Form

Pharmacist Quality Manager, NV Pharmacist in Charge

Title

Signature (copies or stamps not accepted)

4 11 2024

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

wedgewood
PHARMACY

RECEIVED
4/17/24

Fee Processed

April 15, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno NV 89521

RE: Change of Ownership Wedgewood Village Pharmacy LLC
License Number: PH02236

Dear Sir/Madam:

Enclosed please find an application for the change of ownership of Wedgewood Village Pharmacy LLC ("Wedgewood"). Wedgewood is a compounding pharmacy located in Scottsdale, Arizona that compounds sterile and non-sterile medications for veterinary use.

As part of an internal reorganization Wedgewood's parent companies will change in an effort to more streamline the company's organizational structure. The immediate parent of Wedgewood will change to Wedgewood Holdings Inc. In addition, Wedgewood Village Pharmacy LLC will change its name to Wedgewood Pharmacy LLC. The name change is a change in name only and not the result of an entity change. The FEIN and day-to-day operations of Wedgewood will remain the same.

These changes are all internal restructuring and no new external investments are being made into the company. The changes are expected to occur on or about April 30, 2024.

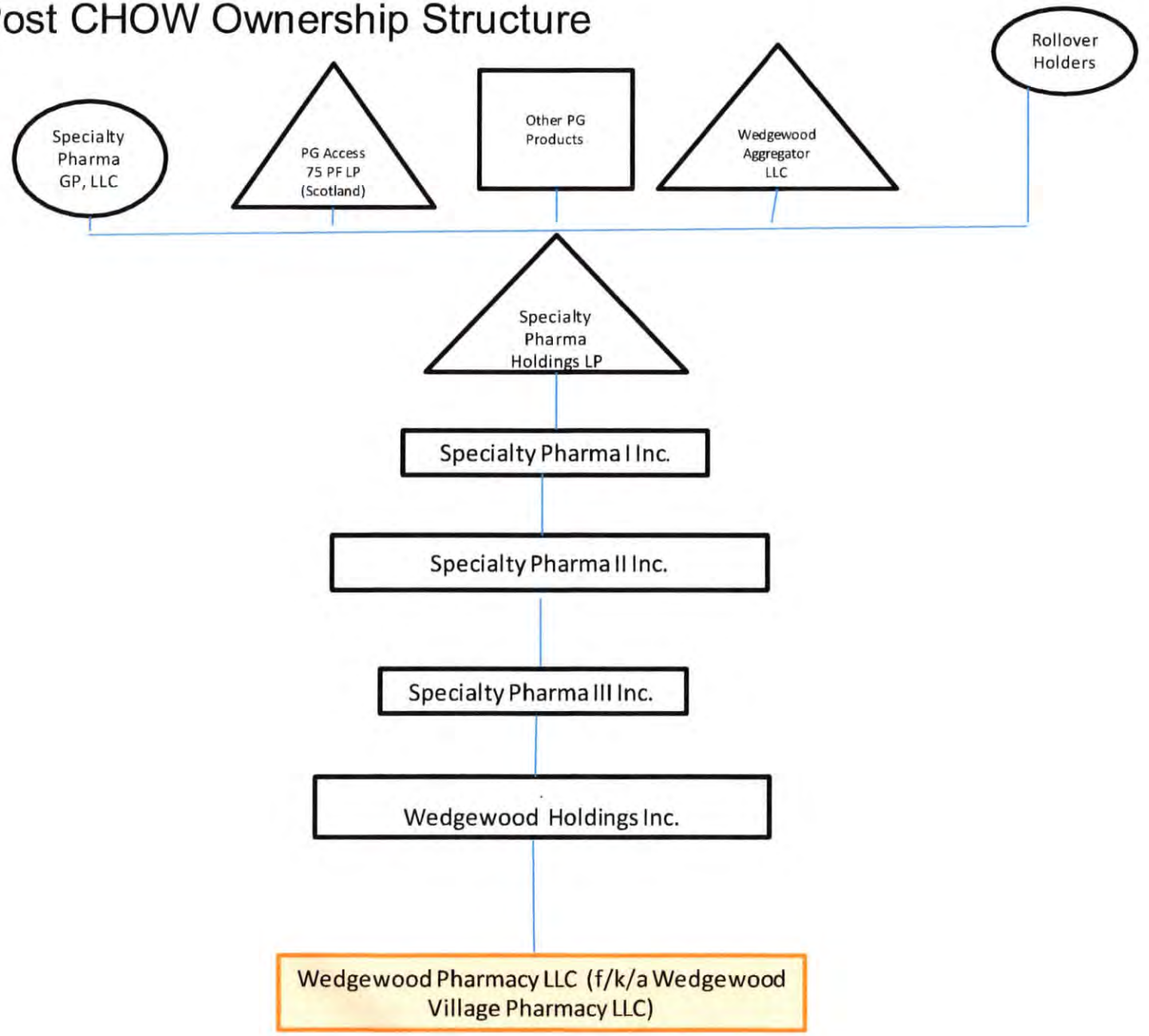
For your reference, we have enclosed before and after organization structure charts demonstrating the nature of the change as well as updated ownership information.

Should you have any questions or require additional information, please do not hesitate to contact me at (559) 361 - 2342 or rachel.taggs@precisionpharmacy.com.

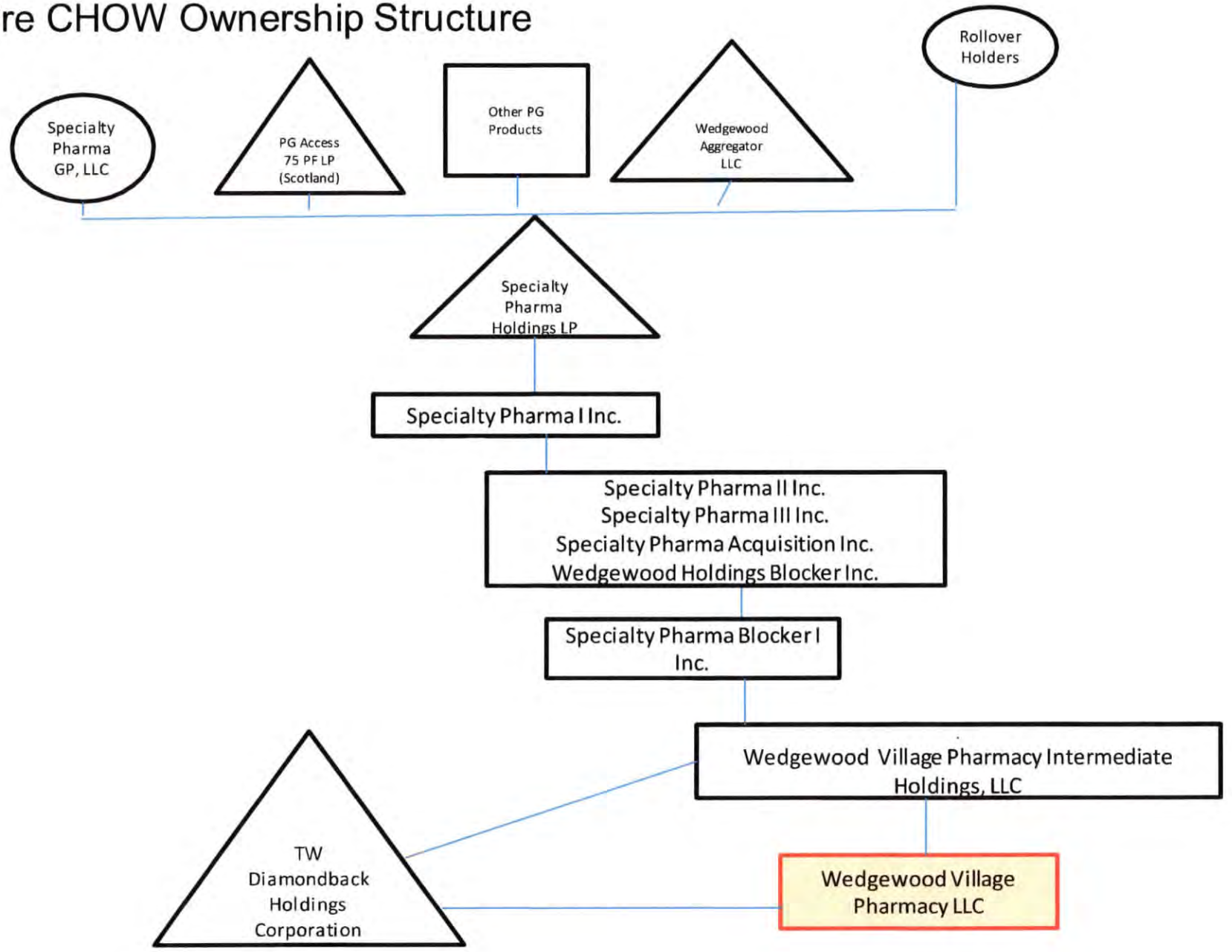
Sincerely,

Rachel Taggs
Senior Compliance Specialist

Post CHOW Ownership Structure



Pre CHOW Ownership Structure



• Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

Section 3: History of Company

3. Has the corporation, any owner(s), shareholder(s) or portner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?

Wedgewood Pharmacy LLC

The list includes prior matters that have previously been reported to the Board in an effort to provide full transparency with the application.

Please note that Wedgewood Pharmacy has operated in two locations so the matters are being reported specific to the applicable facility.

Discipline and Closed Matters for Wedgewood Village Pharmacy LLC, Swedesboro, NJ Location

03/19/2015 – MN/MI/AL Consent Orders

On March 19, 2015, Wedgewood entered into a consent order with the Minnesota Board of Pharmacy (*"Minnesota Consent Order"*). Wedgewood subsequently entered into consent orders with the Michigan Department of Licensing and Regulatory Affairs (*"Michigan LARA"*) and the Alabama Board of Pharmacy ("Alabama BOP") to resolve "sister state" actions that arose out of the Minnesota Consent Order.

The basis for the Minnesota Consent Order are as follows:
Acting on a reasonable and good-faith interpretation of Minnesota law, Wedgewood from its NJ location, dispensed compounds to licensed veterinarians in Minnesota, pursuant to a veterinarian's order for office use. The Minnesota Board asserted that Wedgewood needed a wholesale license to engage in this activity. For the purposes of settlement only, Wedgewood entered into the Minnesota Consent Order whereby it agreed to a $10,000 civil penalty but admitted no wrongdoing.
Wedgewood subsequently entered into a consent order with the Michigan LARA to resolve a "sister state" action brought by Michigan based on the Minnesota Consent Order. Wedgewood entered into a similar consent order with the Alabama BOP to resolve a sister state action brought by Alabama based on the Minnesota Consent Order. There was no finding in the Michigan or the Alabama Consent Order that Wedgewood violated any provisions of Michigan or Alabama state law outside of these states' prohibitions on sister state actions.

10/22/2015 – New Jersey Consent Agreement

On October 22, 2015, Wedgewood Village Pharmacy, Inc., entered into a Consent Agreement with the New Jersey Board of Pharmacy resolving a dispute between the parties on the application of "beyond use dating" regulations for sterile compounds.

This is the same order that is referenced on the Swedesboro, NJ facility's home license however, per the terms of the Agreement, it is not to be construed as discipline and any reimbursement paid to the Board is not considered a fine or other sanction.

10/13/2017 – California Citation & Fine

Issued as a result of an investigation by the CA BOP into an unlicensed individual who fraudulently set up an account with Wedgewood as a veterinarian using valid prescriber license information he acquired unlawfully. An administrative citation was issued and Wedgewood paid a nominal fine.

07/20/2018 - DEA Memorandum of Agreement

While Wedgewood does not consider there to be a restriction on its handling of CDS or disciplinary action, however, out of an abundance of caution, Wedgewood is disclosing the following:

As a condition of issuing Wedgewood located in Swedesboro, New Jersey a DEA manufacturer registration, Wedgewood and the DEA entered into a Memorandum of Agreement ("MOA") for a period of five years (until July 20, 2023) during which Wedgewood agreed not to use the DEA manufacturer license to manufacture or distribute controlled substances for human use. Wedgewood obtained a DEA manufacturer registration for the sole purposes of providing controlled substance compounds solely for veterinarians to use for office use.

12/5/2018 – California Citation

The California Board of Pharmacy issued a non-disciplinary, Administrative Citation with no penalty or fine based on a California Board inspector's interpretation of California regulations. In the Inspector's opinion, providing a 15ml ophthalmic container to a veterinarian for office use exceeded the "reasonable quantity" limitation for office use compounds.

Wedgewood discontinued sales of all 15ml ophthalmic container for office use to California veterinarians. The Board issued a Close Out letter on March 1, 2019. No penalty or fine was assessed.

✓ 6/17/2021 – California Citation & Fine

Received notification of a non-disciplinary, Administrative Citation which was finalized on 07/29/2021. A fine was paid as part of the final citation. The basis for the citation was that Wedgewood did not have the necessary data to support the "beyond use dates" Wedgewood used.

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

On February 21, 2024, the California Board of Pharmacy (the "Board") approved a Stipulated Settlement and Disciplinary Order for Public Reproval entered into with Wedgewood Village Pharmacy LLC relating to claims made by the Board regarding assignment of unsupported beyond use dates and other matters. The Order became effective on March 22, 2024 and Wedgewood agreed to pay the Board $11,054.75 as reimbursement of its costs in connection with this matter.

Discipline and Closed Matters for Wedgewood Village Pharmacy LLC, Scottsdale, AZ Location

10/18/2023 – DEA Letter of Admonition

The Letter of Admonition contains some observations that Wedgewood considers minor and for which Wedgewood has put a corrective plan in place to address.

Rachel Taggs
Sr. Compliance Specialist
Wedgewood Pharmacy

MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

2829 University Ave. SE., #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (651) 201-2837
MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:
Metro and Non-Metro: 800-627-3529
E-Mail Address: Pharmacy.Board@state.mn.us
Web Site: www.pharmacy.state.mn.us

MAR 19 2015

PERSONAL & CONFIDENTIAL

March 16, 2015

Gregory P. Bulinski
Attorney
Bassford Remele
33 South Sixth Street, Suite 3800
Minneapolis, MN 55402-3707

Re: In the Matter of Wedgewood Pharmacy
License No. 262173

Dear Mr. Bulinski,

Enclosed and served upon you in the above-referenced matter is the fully executed Stipulation and Consent issued by the Board of Pharmacy.

Sincerely,

Cody Wiberg

Cody Wiberg, Pharm D, MS, RPh
Executive Director

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullinski, Esq., of Bassford Remele and Rachael G. Pontikes, Esq., of Dunne Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order, . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III, above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MARCY KLISS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

IN THE MATTER OF: WEDGEWOOD VILLAGE PHARMACY, LLC Non-Resident Pharmacy Permit Number: 112625	BEFORE THE ALABAMA STATE BOARD OF PHARMACY CASE NO: 16-L-0066

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Wedgewood Village Pharmacy, LLC ("Wedgewood") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Wedgewood through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Wedgewood has violated the "sister-state" provisions of Alabama law as set out in the Statement of Charges.

2. Wedgewood shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Wedgewood expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975),

§34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Wedgewood further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Wedgewood hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Wedgewood acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Wedgewood's permit, including, but not limited to revocation.

6. Wedgewood acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wedgewood acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 6th of June, 2017.

WEDGEWOOD VILLAGE PHARMACY, LLC

BY: [signature]

ITS: President & CEO

[signature]

Jennifer Clark, attorney for Wedgewood Village Pharmacy, LLC

DONE this the ____ of 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

Buddy Bunch

By: _____

Buddy Bunch, R.Ph., President

By: _____

James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF: WEDGEWOOD VILLAGE PHARMACY, LLC Non-Resident Pharmacy Permit Number: 112626	BEFORE THE ALABAMA STATE BOARD OF PHARMACY CASE NO: 16-L-0066

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Wedgewood Village Pharmacy, LLC
405 Heron Drive
Suite 200
Swedesboro, New Jersey 08085

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on _____, 2016 at _____m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Wedgewood Village Pharmacy, LLC (Wedgewood) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Wedgewood has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Stipulation and Consent Order by the Minnesota Board of Pharmacy on January 4,

2015 attached hereto as Exhibit "A" and/or the Facts set out therein that you shipped drugs to licensed veterinarians in Minnesota without patient specific prescriptions nor the required license to do so.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon the Consent Order entered by the State of Michigan Board of Pharmacy on April 13, 2016 as a result of the filing of an Administrative Complaint, these documents being attached hereto as Exhibits "B" and "C".

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FOUR

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of

the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the _____ day of _____, 2016.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT "A"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullock, Esq., of Hazelford Rennels and Rachael C. Pontikes, Esq., of Dunn Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

11. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified changes, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or omission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MARCY RUSS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT "B"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remele and Rachael G. Pontikes, Esq., of Dunn Morris.

EXHIBIT A page 1 of 7

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes, civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 510, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

EXHIBIT A page 3 of 7

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

EXHIBIT B PAGE 4 of 7

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

EXHIBIT A page 6 of 7

CONSENT:

MARCY KLESS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT A page 7 of 7

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Riggard (P65881)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2016

AGREED TO BY:

Alison Lydell, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 5/21/16

Alan T. Rogalski (P34660)
Attorney for Respondents
Dated: 5/21/2016

ORIGINAL

EXHIBIT "C"

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the matter of

WEDGEWOOD VILLAGE PHARMACY INC.
License Number: 53-01-008041 File Number: 53-15-137239

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs (Complainant) by Kim Gaedeke, Acting Director, Bureau of Health Care Services, files this Complaint against Wedgewood Village Pharmacy Inc. (Respondent Pharmacy) as follows:

1. The Michigan Board of Pharmacy (Board) is an administrative agency established by the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq. Pursuant to section 17768 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent Pharmacy is licensed to practice as a pharmacy in the state of Michigan and has an address of record with Complainant of Swedesboro, New Jersey.

3. On January 21, 2015, the Minnesota Board of Pharmacy (Minnesota Board) executed a Stipulation and Consent Order which ordered Respondent Pharmacy

to pay a $10,000.00 civil penalty. The action was based on Respondent Pharmacy not being licensed as a drug wholesaler by the Minnesota Board and shipping drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. A copy of the Stipulation and Consent Order, marked Exhibit A, is attached and incorporated

COUNT I

The action by the Minnesota Board, as set forth above evidence a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty and constitutes a violation of section 17768(2)(d) of the Public Health Code, supra.

Complainant requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq.

Pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Kim Geedeke, Acting Director, Bureau of Health Care Services, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

Pursuant to section 16231(9) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

DATED: 07/24/2015

Kim Gaedake, Acting Director
Bureau of Health Care Services

Attachment

This is the final page of an Administrative Complaint in the matter of Wedgewood Village Pharmacy Inc., File Number 63-15-197238, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

DWC

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

Wedgewood Village Pharmacy, Inc.
License No. 53-01-008041
/

Complaint No. 53-15-137288

CONSENT ORDER AND STIPULATION

CONSENT ORDER

An administrative complaint was filed with the Disciplinary Subcommittee of the Board of Pharmacy on July 24, 2015, charging Wedgewood Village Pharmacy, Inc. (Respondent) with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended, MCL 333.1101 *et seq.*

The parties have stipulated that the Disciplinary Subcommittee may enter this consent order. The Disciplinary Subcommittee has reviewed the stipulation contained in this document and agrees that the public interest is best served by resolution of the outstanding complaint. Therefore, the Disciplinary Subcommittee finds that the allegations of fact contained in the complaint are true and that Respondent has violated section 17768(2)(d) of the Public Health Code.

Accordingly, for this violation, IT IS ORDERED:

Respondent is FINED $500.00 (Five Hundred Dollars) to be paid by check, money order or cashier's check made payable to the State of Michigan (with complaint number 53-15-137288 clearly indicated on the check or money order), and

shall be payable within 60 days of the effective date of this order. The timely payment of the fine shall be Respondent's responsibility. Respondent shall mail the fine to: Sanction Monitoring, Bureau of Professional Licensing, Enforcement Division -- Compliance Section, Department of Licensing and Regulatory Affairs, P.O. Box 30189, Lansing, Michigan 48909.

This order shall be effective on the date signed by the Chairperson of the Disciplinary Subcommittee or the Disciplinary Subcommittee's authorized representative, as set forth below.

Signed on 4-13-16

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

The parties stipulate as follows:

1. Respondent does not contest the allegations of fact and law in the complaint. Respondent understands that, by pleading no contest, it does not admit the truth of the allegations but agrees that the Disciplinary Subcommittee may treat the allegations as true for resolution of the complaint and may enter an order treating the allegations as true.

2. Respondent understands and intends that, by signing this stipulation, it is waiving the right under the Public Health Code, rules promulgated under the Public Health Code, and the Administrative Procedures Act of 1969, 1969 PA 306,

as amended, MCL 24.201 *et seq.*, to require the Department to prove the charges set forth in the complaint by presentation of evidence and legal authority, and to present a defense to the charges before the Disciplinary Subcommittee or its authorized representative. Should the Disciplinary Subcommittee reject the proposed consent order, the parties reserve the right to proceed to hearing.

3. The Disciplinary Subcommittee may enter the above Consent Order, supported by Board conferee Patti Smeelink, R.Ph. Ms. Smeelink or an attorney from the Licensing and Regulation Division may discuss this matter with the Disciplinary Subcommittee in order to recommend acceptance of this resolution.

4. Conferee Smeelink and the parties considered the following factors in reaching this agreement:

A. Respondent has fully cooperated in this matter and since initially licensed in 2004, Respondent has never had any disciplinary action taken against its Michigan Pharmacy license prior to this incident.

B. Respondent timely reported the Minnesota Board of Pharmacy Stipulation and Consent Order to the Department.

C. The violation of MCL 333.17768(d)(2) as alleged in the Complaint is based solely on a "sister-state" action taken against Respondent's Pharmacy license by the Minnesota Board of Pharmacy that was based on Respondent's former practice in 2012 of dispensing compounded veterinary medications for office-use to licensed veterinarians in Minnesota, which according to the Minnesota Board of Pharmacy, required a wholesaler's license. However, this practice did not implicate Respondent's practice of pharmacy in the State of Michigan and Respondent has not been found to have violated the Michigan Public Health Code or Board of Pharmacy Administrative Rules, except as provided herein.

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Elizondo

Kelly K. Elizondo (P45584)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2016

AGREED TO BY:

Alton Lynch, Pharmacist-in-Charge,
Wedgewood Village Pharmacy
Respondent
Dated: 3/31/16

Alan T. Rogalski (P44660)
Attorney for Respondent
Dated: 3/31/2016

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street 5th Floor
P.O. Box 45029
Newark, New Jersey 07101

By: Megan Cordoma
Deputy Attorney General
Tel. No. (973) 648-4730

FILED
OCT 22 2015
BOARD OF PHARMACY

STATE BOARD OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF
THE REGISTRATION OF

WEDGEWOOD VILLAGE PHARMACY, INC.
Registration No.:28RS00316800

TO OPERATE A PHARMACY
IN THE STATE OF NEW JERSEY

Administrative Action

CONSENT ORDER

This matter was opened to the New Jersey Board of Pharmacy ("the Board") upon receipt of reports of inspection of the facility at Wedgewood Village Pharmacy, Inc. ("Wedgewood") which occurred on November 14 and 15, 2012. The reports document potential violations of the Board's regulations regarding sterile compounding. Wedgewood engages in high risk sterile compounding.

Among other things, the inspection reports highlighted routine professional practices suggesting that thousands of units of medication were dispensed with disregard for the following regulatory requirements:

- Use-by dates exceed 30 days after preparation in violation of N.J.A.C. 13:39-11.11.

- Failure to include date and time of preparation on prescription labels in violation of N.J.A.C. 13:39-11.10(a)(1).

- Failure to include the use-by date and use-by time on prescription labels as required by N.J.A.C. 13:39-11.10(a)(7).

No evidence of contamination was found. Wedgewood denies the allegations of violations and has been fully cooperative with the Board's investigation. There have been significant changes in management of Wedgewood since the time of the events in question. The pharmacy permit holder at the time of these events is now deceased and his wife now holds the permit. Wedgewood has agreed to replace the registered pharmacist-in-charge. Wedgewood represents that it is now in compliance with New Jersey statutes and regulations and with the USP guidelines. Wedgewood further represents that 100% of all sterile compounds are currently being tested for sterility and that all use-by dates are properly supported. Accordingly, the Board has determined that the monitoring requirements imposed herein are sufficient to protect the public health, safety and

welfare.

The parties, having agreed to resolution of this matter without formal proceedings, and Wedgewood, having agreed and given voluntary consent to the within order and waiving any right to a hearing, and the Board finding the within disposition adequately protective of the public health, safety, and welfare, and other good cause having been shown;

IT IS THEREFORE on this 22nd day of OCTOBER, 2015,

ORDERED AND AGREED that

1. Wedgewood shall contract with a third-party monitor (the "Monitor") pre-approved by the Board to review all compounding operations of the pharmacy. For the purposes of this Order, LDT Health Solutions, Inc. is an approved Monitor. Within 30 days of the entry of this Order, the Monitor shall furnish the Board directly with a report which demonstrates review of all processes and procedures, and attests to compliance with all Board regulations and USP standards. Wedgewood shall conduct environmental testing, pressure differential monitoring, and air and surface sampling for bacteria and fungi and make these test results available to the Monitor prior to the Monitor issuing its report and directly to the Board. Wedgewood shall continue to contract with the Monitor and the Monitor will submit reports directly to the Board on the first day of each month until the Monitor

reports directly to the Board that Wedgewood has complied with all recommendations made by the Monitor and is operating in full compliance with all Board regulations and USP standards. All costs associated with the monitoring outlined in this Order shall be the responsibility of, and paid directly by, Wedgewood.

2. Within 30 days of the entry of this order, Wedgewood shall appoint a new pharmacist-in-charge and shall ensure that a pharmacist with sterile compounding expertise (either the pharmacist-in-charge or another employee) directly supervises the daily sterile compounding operations to further ensure the quality and integrity of their products. "Directly supervise" for the purpose of this paragraph means ensure that all proper checks and balances are being performed during the compounding process; help identify and eliminate errors and mistakes; ensure training and testing of personnel testing is occurring; and generally help to ensure that proper aseptic technique is being used to help implement a Quality System and Environment to produce compounded sterile product.

3. Prior to hiring any pharmacist-in-charge or pharmacist to directly supervise daily sterile compounding operations, Wedgewood shall ensure that the individual is competent and that his/her license is not restricted in such a way as to preclude them from fulfilling their job responsibilities.

Wedgewood shall not hire an individual to be pharmacist-in-charge or to directly supervise the daily sterile compounding operations if Wedgewood is aware that the individual is subject to a pending Board investigation.

4. Wedgewood agrees to pay the Board the sum of $500,000.00 in two equal installments due on or before November 31, 2015 and December 31, 2015. This payment will reimburse the Board for attorney's fees and investigative costs and the remainder will be applied toward the Board's ongoing efforts to inspect, investigate and educate pharmacies involved in sterile compounding. Wedgewood and the Board acknowledge and agree that the payment described herein is not a fine, sanction, warning letter or penalty, or payment in lieu thereof. Payment shall be made by bank check, money order, wire transfer or credit card made payable to the New Jersey Board of Pharmacy.

5. This Consent Order shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability of the pharmacy.

NEW JERSEY STATE BOARD OF PHARMACY

By: Thomas F.X. Bender, Jr, RPh
Thomas F.X. Bender,
R.Ph., President

I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.

Ludmilla P Malmberg, Owner
and Permit Holder of
Wedgewood Village Pharmacy

Consent as to form and entry:

Angelo Cifaldi, Esq.
Attorney for
Wedgewood Village Pharmacy

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 13, 2017

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- November 12, 2017: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 27, 2017: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 12, 2017: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 12, 2017.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Ericka Busby
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7731

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 27, 2017 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 12, 2017 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 574-7924.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	$1,000.00

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: November 12, 2017

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
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CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: November 12, 2017

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:	Citation Case No : CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC NRP 1826 Respondent	NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2017 77042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On October 13, 2017, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7017 0530 0001 1516 2087

I declare under penalty of perjury that the forgoing is true and correct.

Executed on October 13, 2017, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NRP 1826

Citation Number : CI 2017 77042

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☑ I contest the Citation and request an Office Conference.

Check One:

☑ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: Margy Ann Bliss

Signature: Margy Ann Bliss Dated: 10/26/17

Address of Service: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: (Business) (856) 832-1303 Residence: (609) 320-5050

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

UPS
1Z 54E 7460 1
6470 45 82
Tracking #
10/26/17 3:11 pm

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 23, 2017

Wedgewood Village Pharmacy
Attention: Alison Lynch
405 Heron Dr., Ste. 200
Swedesboro, NJ 08085

RE: Complaint Investigation CI 2016 72146

Dear Pharmacist-in-Charge:

The Board of Pharmacy has completed its investigation of Wedgewood Village Pharmacy.

As a regulatory agency, when conducting an investigation, the Board must adhere to violations prohibited in pharmacy law. Specifically, the information and documentation obtained during the course of an investigation must clearly demonstrate that a violation of pharmacy law occurred.

The Board's analysis of the information and documentation received did not identify sufficient evidence to determine that a violation of pharmacy law occurred. Accordingly, the Board is closing the matter and will be taking no action against the pharmacy or its licensees.

Although we are closing this matter, please be advised that it is your professional responsibility to assure compliance with all pharmacy laws.

We would like to thank you for your cooperation and assistance. If you should have any questions, please contact the Board at the above address or telephone number.

Sincerely,

VIRGINIA K. HEROLD
Executive Officer

By

Tina Rojas
Complaint Unit Analyst

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
NEW JERSEY DIVISION
CAMDEN RESIDENT OFFICE

IN THE MATTER OF:
Wedgewood Village Pharmacy, LLC
Wedgewood Animal Wellness, LLC
405 Heron Drive
Swedesboro, NJ 08085

DEA Application# W15007898E
DEA Application# W17088272E

MEMORANDUM OF AGREEMENT

On or about 2/5/2015, the Drug Enforcement Administration (DEA) received an application for controlled substance registration (DEA control number W15007898E) from Wedgewood Village Pharmacy, LLC 405 Heron Drive, Swedesboro, NJ 08085. On or about 8/18/2017, DEA received another application for controlled substance registration (DEA control number W17088272E) from Wedgewood Animal Wellness LLC, 405 Heron Drive, Swedesboro, NJ 08085.

This Memorandum of Agreement (MOA) between the DEA and Wedgewood Village Pharmacy LLC establishes terms and conditions under which the DEA will issue a registration to Wedgewood Village Pharmacy LLC as a Manufacturer to handle Schedules III through V controlled substances subject to the terms set forth below in this Memorandum of Agreement. This MOA applies only to the manufacturing registration to be issued to Wedgewood Village Pharmacy LLC.

Wedgewood agrees to enter into this MOA with the DEA for a period of five (5) years from the date the MOA is signed and fully executed. The MOA shall be considered fully executed when all parties to the MOA have signed and dated the MOA.

Wedgewood agrees to not manufacture or distribute any controlled substances for human use under the DEA issued manufacturing registration.

Wedgewood agrees to contact DEA immediately if there is any change to their business practice of selling controlled substances for animal use only pursuant to their DEA issued manufacturing registration.

Wedgewood shall abide by and obey all federal, state, and local laws and requirements relating to controlled substances.

Wedgewood agrees to immediately notify DEA if there is any change of status in its State of New Jersey license and/or State Controlled Dangerous Substance license, including any actions filed against these licenses.

Wedgewood agrees to allow DEA to conduct onsite inspections, including inspections of its controlled substances records, without prior notice pursuant to a Notice of Inspection of Controlled Premises and without requiring DEA to obtain an Administrative Inspection Warrant, Search Warrant, or other means of entry

Wedgewood agrees that this MOA constitutes the entire agreement between Wedgewood and DEA, and may only be modified or amended by a subsequent document executed in the same manner by both parties in writing.

Wedgewood shall report any professional, civil, or criminal action concerning controlled substances that is pending or taken against the firm by any state, federal, or professional agency or governing body to DEA, Camden Resident Office.

Wedgewood shall maintain a complete and accurate record of all controlled substances manufactured or distributed pursuant to this manufacturing registration.

Wedgewood agrees by executing this MOA, it waives judicial review, and will not challenge or contest the validity of any terms or conditions of this agreement.

The parties further agree that should Wedgewood violate any terms or conditions of this agreement, such violation may constitute grounds for the revocation, or the revocation and immediate suspension, of Wedgewood's DEA manufacturing registration. Nothing in this MOA shall preclude Wedgewood from contesting any subsequent Order to Show Cause, or Order to Show Cause and Immediate Suspension, of its DEA manufacturing registration as permitted under the Controlled Substances Act and the Administrative Procedure Act. Nothing in this MOA shall be construed as a waiver on the part of DEA to utilize any violations, past or subsequent, as grounds for revocation of Wedgewood's DEA manufacturing registration, either by themselves or in conjunction with other grounds, in the event that future DEA administrative proceedings become necessary. Furthermore, DEA is not precluded from introducing this MOA at any subsequent DEA administrative proceeding.

DEA agrees to promptly approve Wedgewood's application for a manufacturing registration, control# W15007898E, upon the signing of this MOA by both parties.

The parties agree that Wedgewood's application, control# W17088272E is withdrawn effective the execution of this agreement.

The responsible Wedgewood official below acknowledges and states that s/he has read the foregoing and understands and agrees with the contents herein and that s/he has signed this MOA.

The parties enter into this MOA with the understanding that the Drug Enforcement Administration and Wedgewood Village Pharmacy LLC will abide by its contents in good faith.

Wedgewood Village Pharmacy, LLC — Date: 7/20/18

FOR THE DRUG ENFORCEMENT ADMINISTRATION

Nancy Coffey — Date
Diversion Program Manager
New Jersey Division

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2016 73882
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2016 73882	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7938

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2018 82132
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference rnust be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal rnust be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2018 82132	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7945

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT

Christina Metzen

Associate Enforcement Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2018 82132
NRP 1826

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2018 82132 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NRP 1826
CITATION AND FINE CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4678

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2016 73882
NSC 100970

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2016 73882 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NSC 100970
CITATION AND FINE CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4685

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

Jennifer Sevilla

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 90874
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2020 90874

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, June 17, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9670

I declare under penalty of perjury that the forgoing is true and correct.

Executed on June 17, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2020 90874	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

CITATION ISSUED ON: June 17, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation and Fine, Order of Abatement ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation and indicates, within the Order of Abatement, information and/or material to be submitted to the Board.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- July 17, 2021: Unless the Citation is contested, Proof of Abatement and payment of fine(s) must be received by the Board, or as directed in Order of Abatement at the bottom of your citation.
- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), timely payment of any fine(s) and the submission of Proof of Abatement shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations title 16 section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2020 89042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, April 28, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Order of Abatement, Proof of Abatement, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9687

I declare under penalty of perjury that the forgoing is true and correct.

Executed on April 28, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

Citation Number	Name, License No
CI 2020 89042	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1735.2 subd. (i)(3)	Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...	$2,500.00

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

In addition to the issued citation, Wedgewood Village Pharmacy shall provide (1) payment in the amount of $2,500.00 and (2) justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued.

If Wedgewood Village Pharmacy fails to provide justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued, this shall constitute a ground for revocation or suspension of your license, permit, or registration.

CITATION ISSUED ON: June 17, 2021	TOTAL AMOUNT OF FINE(S): $2,500.00
PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: July 17, 2021	

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 29, 2021

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

This is in response to the administrative fine and proof of abatement provided to the board for the above referenced citation. The payment and documentation have been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Enforcement Manager, Susan Cappello at (916) 518-3008.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

U. S. Department of Justice
Drug Enforcement Administration
3439 East University Drive
Phoenix, Arizona 85034

www.dea.gov

October 16, 2023

Marcy Bliss, CEO
Wedgewood Village Pharmacy
7631 East Indian School Road, Suite 105
Scottsdale, Arizona 85251

SENT VIA EMAIL TO AZ-COMPLIANCE@WEDGEWOODPHARMACY.COM

Dear Ms. Bliss:

On July 11-13, 2023, Investigators from the Drug Enforcement Administration (DEA), Phoenix Division, conducted an investigation at your registered location at 7631 East Indian School Road, Suite 105, Scottsdale, Arizona 85251 under DEA Certificate of Registration (COR) RD0541878, as a manufacturer handling controlled substances in schedules 2, 2N, 3, 3N, 4, and 5 as well as List 1 chemicals. The investigation revealed your failure to comply with the requirements of Title 21 Code of Federal Regulations (C.F.R.), in violation of Title 21 United States Code (U.S.C.). The following violations were noted during the investigation:

1. You failed to maintain complete and accurate records of controlled substances as required by Title 21 C.F.R. § 1304.21(a) and Title 21 U.S.C. § 827(a)(3) in violation of Title 21 U.S.C. § 842(a)(2). The audit conducted by the Investigators showed both shortages and overages throughout the manufacturing process. The initial inventory provided during the audit was inaccurate for one of the controlled substances audited. Wedgewood failed to keep an accurate record of all movement of the controlled substances during the manufacturing process. The audit revealed the following:

CONTROLLED SUBSTANCE	DIFFERENCE	PERCENTAGE
Raw Material:		
- Hydrocodone Powder	+11.349g	+1.32%
- Morphine Sulfate Powder	-0.784g	-0.17%
- Phenylpropanolamine (PPA)	-303.683g	-1.52%
- Midazolam Powder	-16.174g	-1.55%
- Pregabalin Power	-11.959g	-0.35%
- Buprenorphine Powder AC	-0.388g	-0.07%
- Buprenorphine Powder GC	-5.985g	-0.35%
Batch Records:		
- Hydrocodone 2.5mg capsule	- 30mg	-0.27%
- Morphine Sulfate 15mg/ml)	+334mg	+0.12%
- Phenylpropanolamine(PPA)37.5mg capsules	-170mg	-0.05%
- Midazolam 200mg/ml nasogel	-294mg	-0.09%

- Pregabalin 10mg	-846mg	-0.59%
- Pregabalin 20mg	-260mg	-0.27%
- Buprenorphine .3mg unflavored	+32.44mg	+0.45%
- Buprenorphine .3mg flavored	+122.683mg	+0.18%
- Buprenorphine .6mg	-20mg	-0.01%
Finished Products:		
- Hydrocodone 2.5mg capsule	0	0%
- Morphine Sulfate 15mg/ml)	0	0%
- Phenylpropanolamine(PPA) 37.5mg cap	0	0%
- Midazolam 200mg/ml nasogel	0	0%
- Pregabalin 10mg	+58 capsules	+0.41%
- Pregabalin 20mg	0	0%
- Buprenorphine .3mg unflavored	-13.75 bottles	-0.10%
- Buprenorphine .3mg flavored	-2.202 bottles	-0.03%
- Buprenorphine .6mg	0	0%

2. All in-process substances should be returned to the controlled substances storage area at the end of the workday. Wedgewood failed to do so and stored the raw and in-process controlled substances in the manufacturing area, in violation of Title 21 C.F.R. § 1301.73(a).

3. The initial inventory provided to investigators during the audit was inaccurate for one of the controlled substances audited. Title 21 C.F.R. § 1304.21(a) requires your inventory to contain a complete and accurate records of all controlled substances on hand.

This letter serves as formal notification of the above findings which constitute violations of the Controlled Substances Act (C.S.A.) and the regulations promulgated hereunder. DEA Diversion Investigators advised you of the regulatory and statutory requirements on July 20, 2023, and you are being afforded the opportunity to comply. Please advise this office in writing within 30 days of receipt of this letter, describing the actions taken or planned to correct these violations and to prevent the reoccurrence. You may email your response to Diversion Investigator Nicole Nelson at Nicole.K.Nelson@dea.gov.

If you have any questions concerning this matter, please contact Diversion Investigator Nicole Nelson at (480) 868-0023 or Group Supervisor Lynnette Wingert at (571) 362-5600. For additional information and resources, please visit the Diversion Control Division website at www.DEAdiversion.usdoj.gov.

Sincerely,

Cheri Oz
Special Agent in Charge

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 21, 2024

CERTIFIED MAIL

Wedgewood Village Pharmacy
Attn: Marcy Ann Bliss, CEO
405 Heron Drive
Swedesboro, NJ 08085

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy LLC, dba Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

Dear Ms. Bliss:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to pages 5 – 6 of the document.

Effective at 5:00 p.m. on March 22, 2024, Nonresident Pharmacy Permit Nos. NRP 2526 & NRP 1826 and Nonresident Sterile Compounding Permit Nos. NSC 101673 & NSC 100970 issued to Wedgewood Village Pharmacy, shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By 

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Kristina T. Jarvis, DAG
Derek Shaffer, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
Wedgewood Village Pharmacy Attn: Marcy Ann Bliss, CEO 405 Heron Drive Swedesboro, NJ 08085	9589 0710 5270 0843 9755 17
Quinn Emanuel Urquhart & Sullivan, LLP Attn: Derek Shaffer, Esq. 1300 I St., NW., Ste. 900 Washington, D.C. 20005	9589 0710 5270 0843 9755 24

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 21, 2024, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 21, 2024, at Sacramento, California

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

WEDGEWOOD VILLAGE PHARMACY LLC; dba
WEDGEWOOD VILLAGE PHARMACY;
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 2526,
Nonresident Sterile Compounding Permit No. NSC 101673; and

WEDGEWOOD VILLAGE PHARMACY LLC;
WEDGEWOOD VILLAGE PHARMACY
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondents

Agency Case No. 7286

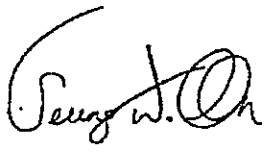
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 22, 2024.

It is so ORDERED on February 21, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC; 405 Heron Drive Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526, Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; ALISON LYNCH, PIC; 405 Heron Drive, Suite 200 Swedesboro, NJ 08085**	Case No. 7286 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970

Respondents.

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Kristina T. Jarvis, Deputy Attorney General.

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge (Respondent Original Licensee). On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

6. Respondent is represented in this proceeding by attorney Derek Shaffer whose address is: 1300 I Street NW, Suite 900, Washington D.C. 20005.

JURISDICTION

7. Accusation No. 7286 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on April 27, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. On July 26, 2023, Complainant filed a First Amended Accusation. A copy of First Amended Accusation No. 7286 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7286. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

9. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

10. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

11. NRP 1826 and NSC 101673 have been cancelled, and the Board confirms that there are no pending allegations or investigations against these licenses, and therefore no future administrative or disciplinary action is contemplated.

CULPABILITY

12. Respondent understands and agrees that the charges and allegations in Accusation No. 7286, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits.

13. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

14. Respondent agrees that its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

15. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action

between the parties, and the Board shall not be disqualified from further action by having considered this matter.

16. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

17. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

18. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970, Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673 issued to Respondents shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7286, attached as exhibit A.

Cost Recovery. No later than 1 YEAR from the effective date of the Decision, Respondent shall pay $11,054.75 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Nonresident Pharmacy Permit NRP 2526, or Nonresident Sterile Compounding Permit No. NSC 101673 until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 7286, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Derek Shaffer. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/2/2024 | 1:23 PM PST

WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, and TW DIAMONDBACK HOLDINGS CORPORATION, dba WEDGEWOOD VILLAGE PHARMACY LLC;

DocuSigned by:
By: MARCY ANN BLISS Marcy Ann Bliss
25DA168EA289425...

Title: CEO
Respondent

I have read and fully discussed with Respondent Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation, dba Wedgewood Village Pharmacy LLC, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 1/4/2024 | 7:34 AM PST

DocuSigned by:
Derek Shaffer
DEREK SHAFFER
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: January 11, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

SA2022301557

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **WEDGEWOOD VILLAGE PHARMACY LLC;** **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **MARCY ANN BLISS, CEO;** **JOSEPH COSTA, COO;** **ALISON LYNCH, PIC;** **405 Heron Drive** **Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526,** **Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC;** **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **LUDMILLA MALMBERG, Chairman;** **MARCH ANN BLISS, CEO;** **JOCELYN ROSE STANLEY, Secretary;** **THOMAS J. FORMOLO, Secretary;**	Case No. 7286 **ACCUSATION**

EDWARD MICHAEL LHEE, Secretary;
ALISON LYNCH, PIC;
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondent.

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Chairman, Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge. On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Ludmilla Malmberg, Chairman,Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Original Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

JURISDICTION

6. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4011 of the Code states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

8. Section 4300 of the Code states in pertinent part:

(a) Every license issued may be suspended or revoked.

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

9. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not

deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

10. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

11. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(c) Gross negligence.

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency....

REGULATORY PROVISIONS

12. California Code of Regulations, title 16, (Regulations) section 1735.2 states in pertinent part:

...

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

...

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

...

(*l*) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

13. Regulations section 1735.3 states in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

...

(2) A compounding log consisting of a single document containing all of the following:

...

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply....

COST RECOVERY

14. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG PREPARATIONS

15. Tacrolimus Ophthalmic Suspension is an eye drop generally prescribed to dogs to treat dry eyes, particularly when caused by low tear production or tears of poor quality. It is a dangerous drug pursuant to Code section 4022.

16. Protirelin is an injectable drug product generally prescribed for horses as a thyrotropin-releasing hormone in order to test for certain metabolic disorders or illnesses. It is a dangerous drug pursuant to Code section 4022.

17. Cyclosporine in MCT oil solution is an eye drop generally prescribed to dogs. It is used to decrease inflammation in the eye and tear glands and increase tear production. It is a dangerous drug pursuant to Code section 4022.

18. Edetate Disodium (EDTA) is a chelating agent generally prescribed to treat corneal ulcers in dogs, cats, and horses. It is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

19. Respondents own and operate a nonresident pharmacy which also possesses a nonresident sterile compounding pharmacy permit, and is located in the State of New Jersey.

20. On or about April 1, 2021, due to a change in the ownership structure of certain parent corporations that own the corporations that own Respondent Original Licensee, successor licensees, both a nonresident pharmacy permit and a nonresident sterile compounding pharmacy permit, were issued to the same immediate ownership structure. Nearly all of the immediate owners and officers of Respondent Original Licensee remained with Respondent Successor Licensee. The conduct set forth in this accusation came to the attention of the Board due to the change of ownership inspection that is required by pharmacy law. Therefore, all of the actions were taken on dates on which Respondent Original Licensee was the owner and operator of the pharmacy. However, since the immediate ownership structure did not change, the owners and operators of Respondent Successor Licensee are responsible for the actions of Respondent Original Licensee.

21. Respondents specialize in veterinary compounding.

22. On January 1, 2017, the Board's sterile compounding regulations became effective.

23. In 2017, Board inspector S.P. issued a written warning to Respondents due to Respondents issuing many of its drug preparations extended beyond use dates (BUDs) without the appropriate data to support those BUDs.

24. In 2018, and again in 2020, during inspections of Respondents facility, Board inspector S.P. discussed with Respondents the documentation Respondents needed to provide, obtain, or test for, in order determine and assign extended BUDs and noted that Respondents had not obtained, tested for, or provided this documentation such that the extended BUDs were still inappropriate.

25. After the 2020 inspection, the Board issued a citation to Respondents for providing 120-day extended BUDs without having the tests and studies required to support the extended BUDs.

///

26. On and between approximately March 17, 2021, and May 28, 2021, Board Inspector M.V. conducted a change of ownership inspection regarding Respondents as discussed in additional depth, above. Due to the COVID-19 pandemic, the inspection was conducted remotely via records review. The investigation report is dated March 1, 2022 (March 1, 2022 Inspection Report).

27. On or about March 19, 2021, Board Inspector M.V. requested five specific compounding logs for review, including certificates of analyses, end-product release testing, documentation supporting any extended BUDs assigned to preparations, sample labels, and training records for Respondents' compounding pharmacist and compounding pharmacy technician. M.V.'s review of just these five compounding logs lead to the causes for discipline set forth below.

FIRST CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Dates)

28. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations 1735.2, subdivision (i). The circumstances are as follows:

A. On or about July 1, 2020, Respondents compounded 623 bottles of Tacrolimus 0.03% ophthalmic aqueous suspensions and gave an extended BUD of 160 days. Respondents only had data to support a 45-day BUD for this drug product.

B. On or about November 27, 2020, Respondents compounded 581 bottles of Cyclosporine 2% in MCT oil ophthalmic solutions and gave an extended BUD of 180 days. Respondents only had data to support a 45-day BUD for this drug product.

C. On or about February 8, 2021, Respondents compounded 353 vials of Protirelin Acetate 1mg/ml injectable solution and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for this product.

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D. On or about March 10, 2020, Respondents compounded 53 bottles (15mL) of Edetate Disodium and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for the product.

SECOND CAUSE FOR DISCIPLINE

(Incomplete Compounding Records)

29. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations section 1735.3, subdivision (a)(2). The circumstances are that Respondents' compounding logs reviewed by Board Inspector M.V. failed to list the manufacturers of the drug components Respondents used for compounding.

THIRD CAUSE FOR DISCIPLINE

(Gross Negligence)

30. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (c), in that Respondents committed acts constituting gross negligence when Respondents assigned extended BUDs without having the required data to support those BUDs.

FOURTH CAUSE FOR DISCIPLINE

(Knowingly Making or Signing a False Document)

31. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents knowingly made or signed false documents when Respondents assigned extended BUDs without having the required data to support those BUDs.

FIFTH CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

32. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption when Respondents continued to assign extended

BUDs and ship the compounded drugs to patients without having the required data to support those BUDs.

DISCIPLINARY CONSIDERATIONS

33. On or about June 17, 2021, Citation number CI 2020 90874 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation did not order a fine, it was not appealed, and it is final.

34. On or about June 17, 2021, Citation number CI 2020 89042 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation ordered a $2,500 fine, and required proof of abatement regarding justification for assigning extended BUDs for antibacterial eye ointment. The citation was not appealed and is final.

35. On or about December 5, 2018, Citation number CI 2018 82132 was issued to Respondent Original Licensee's Nonresident Pharmacy permit f or violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

36. On or about December 5, 2018, Citation number CI 2016 73882 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

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37. On or about October 13, 2017, Citation number CI 2017 77042 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Code section 4059.5, subdivision (b), for selling prescription items to individual. S.G. who was not authorized to purchase these items. S.G. represented himself as a physician and Respondent Original Licensee failed to note the discrepancy between S.G.'s address and the address of the physician he was impersonating. The citation ordered a $1,000 fine, it was not appealed, and it is final.

OTHER MATTERS

38. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 2526 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 101673 issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC then Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, and if Ludmilla Malmberg, Marcy Ann Bliss, Joseph Costa, and Alison Lynch are proven to have knowledge of or have participated in the conduct, then each shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Nonresident Pharmacy Permit number NRP 1826, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

2. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 100970, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

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3. Revoking or suspending Nonresident Pharmacy Permit number NRP 2526, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

4. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 101673, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

5. Prohibiting Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Ludmilla Malmberg from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

7. Prohibiting Marcy Ann Bliss from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

8. Prohibiting Joseph Costa from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

9. Prohibiting Alison Lynch from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

10. Ordering Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Marcy Ann Bliss, and Joseph Costa to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

///

11. Taking such other and further action as deemed necessary and proper.

DATED: 4/5/2023

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2023.04.15 07:02:07 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2022301557
Wedgewood Acc.docx



GOVERNMENT CODE - GOV

TITLE 2. GOVERNMENT OF THE STATE OF CALIFORNIA [8000 - 22980] *(Title 2 enacted by Stats. 1943, Ch. 134.)*

DIVISION 3. EXECUTIVE DEPARTMENT [11000 - 15986] *(Division 3 added by Stats. 1945, Ch. 111.)*

PART 1. STATE DEPARTMENTS AND AGENCIES [11000 - 11898] *(Part 1 added by Stats. 1945, Ch. 111.)*

CHAPTER 5. Administrative Adjudication: Formal Hearing [11500 - 11529] *(Heading of Chapter 5 amended by Stats. 1995, Ch. 938, Sec. 22.)*

11521. (a) The agency itself may order a reconsideration of all or part of the case on its own motion or on petition of any party. The agency shall notify a petitioner of the time limits for petitioning for reconsideration. The power to order a reconsideration shall expire 30 days after the delivery or mailing of a decision to a respondent, or on the date set by the agency itself as the effective date of the decision if that date occurs prior to the expiration of the 30-day period or at the termination of a stay of not to exceed 30 days which the agency may grant for the purpose of filing an application for reconsideration. If additional time is needed to evaluate a petition for reconsideration filed prior to the expiration of any of the applicable periods, an agency may grant a stay of that expiration for no more than 10 days, solely for the purpose of considering the petition. If no action is taken on a petition within the time allowed for ordering reconsideration, the petition shall be deemed denied.

(b) The case may be reconsidered by the agency itself on all the pertinent parts of the record and such additional evidence and argument as may be permitted, or may be assigned to an administrative law judge. A reconsideration assigned to an administrative law judge shall be subject to the procedure provided in Section 11517. If oral evidence is introduced before the agency itself, no agency member may vote unless he or she heard the evidence.

(Amended by Stats. 2004, Ch. 865, Sec. 34. Effective January 1, 2005.)

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH PH04567	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: specialty	☑ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☑ Other: specialty

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☑ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Access Therapy Center

Physical Address: 304 Merchant Lane,

City: Pittsburgh State: PA Zip: 15205

Mailing Address (if different from physical address): 304 Merchant Lane,

City: Pittsburgh State: PA Zip: 15205

Telephone: (412) 428-6223 Toll Free # (NAC 639.708, NRS 639.23286): (888) 796-8154

Fax: (877) 370-0142 Contact Email: licensing@raremedpsc.com

Website: www.raremed.com

Nevada Business License # (if applicable) NA-Not Applicable

Supervising/Managing Pharmacist Name (NRS 639.220): John James Coll, Jr.

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24157

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: John James Coll, Jr.	NV Pharmacist Registration #: 24157
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA-Not Applicable	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA-Not Applicable

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Pennsylvania

Parent Company (if any): PSC Holding Co LLC

Corporation/Organization Name: Patient Service Center LLC

Mailing Address: 304 Merchant Lane,

City: Pittsburgh State: PA Zip: 15205

Telephone: (412) 428-6223 Email: licensing@raremedpsc.com

Contact Person Name: Erik J. Heikkenen, Principal Consultant

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: NA-Not Applicable

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA-Not Applicable

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Access Therapy Center (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Brian D. Smith

Print Name of Authorized Person

Brian D. Smith

Original signature of Authorized Person (copies or stamps not accepted)

7/15/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Brian D. Smith hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Access Therapy Center (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Brian D Smith

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 17 day of July, 2024

Notary Public

KELLY PERONE
Notary Public, State of New Jersey
My Commission Expires
October 27, 2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian D. Smith, President

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Brian D Smith

Original signature of Authorized Person (copies or stamps not accepted)

7/15/24

Date

Board Use Only	Date Received: 7/17/24	Amount: $500-CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Access Therapy Center

Pharmacy/Wholesaler License # (if applicable): pending

Physical Address: 304 Merchant Lane

City: Pittsburgh, State: PA Zip: 15205

Mailing Address (if different from physical address): 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Telephone: (412) 428-6223 Website: www.raremed.com

Licensing Company Email: licensing@raremedpsc.com

Section 2: Personal Information

First: John Middle: James Last: Coll, Jr.

Alias(es, nicknames, name changes, etc.): NA-Not Applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Fox Run Drive

City: Venetia State: PA Zip: 15367

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	NA	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Duquesne University			08/16 - 05/20
Address	**City**	**State**	**Zip**
600 Forbes Ave	Pittsburgh	PA	15282
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name			From - To (MM/YY – MM/YY)
Duquesne University			08/09 - 05/13
Address	**City**	**State**	**Zip**
600 Forbes Ave	Pittsburgh	PA	15282
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name			From - To (MM/YY – MM/YY)
Seton La Salle High School			
Address	**City**	**State**	**Zip**
100 McNeilly Road	Pittsburgh	PA	15226
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/21 - present	[redacted]Fox Run Drive	Venetia	PA	15367
02/15/ - 01/21	[redacted] Cheston Street	Pittsburgh	PA	15227
05/10 -002/15	[redacted] South 12th Street	Pittsburgh	PA	15227
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Patient Service Center LLC			12/23 - present
Business Address	**City**	**State**	**Zip**
304 Merchant Lane,	Pittsburgh	PA	15205
Phone	**Title**		**Number of Employed Hours**
(412) 428-6223	Pharmacist-in-Charge / Manger, Pharmacy Operations		1220

Description of Duties

dispense prescriptions, counsel patients, oversee technicians, manage inventories, maintain records, oversee operations, review regulatory compliance, maintain vendor relationships, manage SOP and QA positions

Business Name			From - To (MM/YY – MM/YY)
RareMed Solutions			03/21 - 12/23
Business Address	**City**	**State**	**Zip**
200 Industry Drive,	Pittsburgh	PA	15205
Phone	**Title**		**Number of Employed Hours**
(833) 676-7273	Manager, Pharmacy Opertions		6240

Description of Duties

dispense prescriptions, counsel patients, oversee technicians, manage inventories, maintain records, oversee operations, review regulatory compliance, maintain vendor relationships, manage SOP and QA positions

Business Name			From - To (MM/YY – MM/YY)
Rite Aid Pharmacy			07/20 - 03/21
Business Address	**City**	**State**	**Zip**
2501 Saw Mill Run Blvd	Pittsburgh	PA	15234
Phone	**Title**		**Number of Employed Hours**
(412) 882-0500	Staff Pharmacist		1350

Description of Duties

dispense prescriptions, counsel patients, oversee technicians, manage inventories, maintain records,

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	NA	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, John James Coll, Jr., **certify that as the designated representative for**

Access Therapy Center,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JC I am at least 21 years of age;
3. JC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

John James Coll, Jr.
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/12/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John James Coll, Jr.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/12/24

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Allegheny

I, John Coll J, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/12/24

Date

Subscribed and Sworn to before me this 12 day of July.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
AMY DOVIE - Notary Public
Beaver County
My Commission Expires October 21, 2026
Commission Number 1427778

(Seal)

Personal History Application

N/A – Not Applicable. Please be advised Patient Service Center, LLC dba Access Therapy Center ("Access Therapy Center") is a 100% wholly owned subsidiary of, of Parent Corporation and Sole Member PSC Holding Co LLC. There are no individual or person with ownership in Access Therapy Center.

Owners and Officers

Name and Title	Business Address and Telephone	Home Address and Telephone	Date of Birth	SSN or FEIN	Ownership %
PSC Holding Co LLC Parent / Sole Member	200 Industry Drive Pittsburgh, PA 15205 (888) 796-8154	[redacted] Industry Drive Pittsburgh, PA 15205 [redacted]	NA	[redacted]	100%
Brian D. Smith President	1000 US Highway 202 South Raritan, NJ 08869 (908) 927-7325	[redacted] Spruce Drive Doylestown, PA 18902 [redacted]	[redacted]	[redacted]	0%
Amy Shah Vice President	1000 US Highway 202 South Raritan, NJ 08869 (908) 927-7325	[redacted] Ridgeview Circle Princeton, NJ 08540 [redacted]	[redacted]	[redacted]	0%

No Managers. Entity Member Managed

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	Patient Service Center LLC
Request Type:	Subsistence Certificate
Request No.:	037303227
Receipt No.:	001084455
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	July 29, 2023
Status:	Active

Issuance Date: June 07, 2024
File No.: 0013534450

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

Patient Service Center LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

ACCESS THERAPY CENTER

304 MERCHANT LANE
PITTSBURGH, PA, 15205

Phone:
Owner:

LICENSE

License No: AA0005068316 (PP483136)
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business

Inspection Date: 02/09/2024
Inspection Result: Passed

Remarks:

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

If this is a New Business Inspection, this PASS inspection form will serve as a temporary authority to operate pending final review and approval by the State Board. The temporary authority must be prominently displayed and will expire upon receipt of a properly issued license or six months from the date of inspection.

CORY ULISSE	2/9/2024 10:58:00 AM	John James Coll - RP455047
Signature of Inspector	Date/Time	Signature of Owner/Representative

PA State Board of Pharmacy
·PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

ACCESS THERAPY CENTER

304 MERCHANT LANE
PITTSBURGH, PA, 15205

Phone:
Owner:

LICENSE

License No: AA0005068316 (PP483136)
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business

Inspection Date: 02/09/2024
Inspection Result: Passed

Remarks:

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	NO
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

Commonwealth of Pennsylvania Department of State
Bureau of Professional and Occupational Affairs

Pharmacy

License Number
PP483136

Expiration Date
08/31/2025

Active

ACCESS THERAPY CENTER
JOHN JAMES COLL
304 MERCHANT LANE
PITTSBURGH, PA 15205

OFFICIAL DOCUMENT

READ THE FOLLOWING INFORMATION CAREFULLY CONCERNING YOUR LICENSE:

1. SIGN THE WALLET CARD AND CERTIFICATE WHERE INDICATED.
2. DETACH THE WALLET CARD AND CERTIFICATE AT PERFORATION.

Pennsylvania Licensing System (PALS)

Visit our website at: www.pals.pa.gov to renew your license, change your personal or license address, or order duplicate licenses.

ACCESS THERAPY CENTER
JOHN JAMES COLL
304 MERCHANT LANE
PITTSBURGH, PA 15205

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO BOX 2649 Harrisburg PA 17105-2649

23 0211996

License Type
Pharmacy

ACCESS THERAPY CENTER
JOHN JAMES COLL
304 MERCHANT LANE
PITTSBURGH, PA 15205

License Status
Active

Initial License Date
11/02/2023

Expiration Date
08/31/2025

License Number
PP483136

Arion R. Claggett

Acting Commissioner Arion R. Claggett

Signature

ALTERATION OF THIS DOCUMENT IS A CRIMINAL OFFENSE UNDER 18 PA.C.S.§. 4911

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

07/09/2024

License Information

ACCESS THERAPY CENTER

304 MERCHANT LANE
PITTSBURGH, Pennsylvania 15205

Board/Commission:	State Board of Pharmacy	Status Effective Date:	11/02/2023
LicenseType:	Pharmacy	Issue Date:	11/02/2023
Specialty Type:		Expiration Date:	08/31/2025
License Number:	PP483136	Last Renewal:	
Status:	Active		

Prerequisite Information

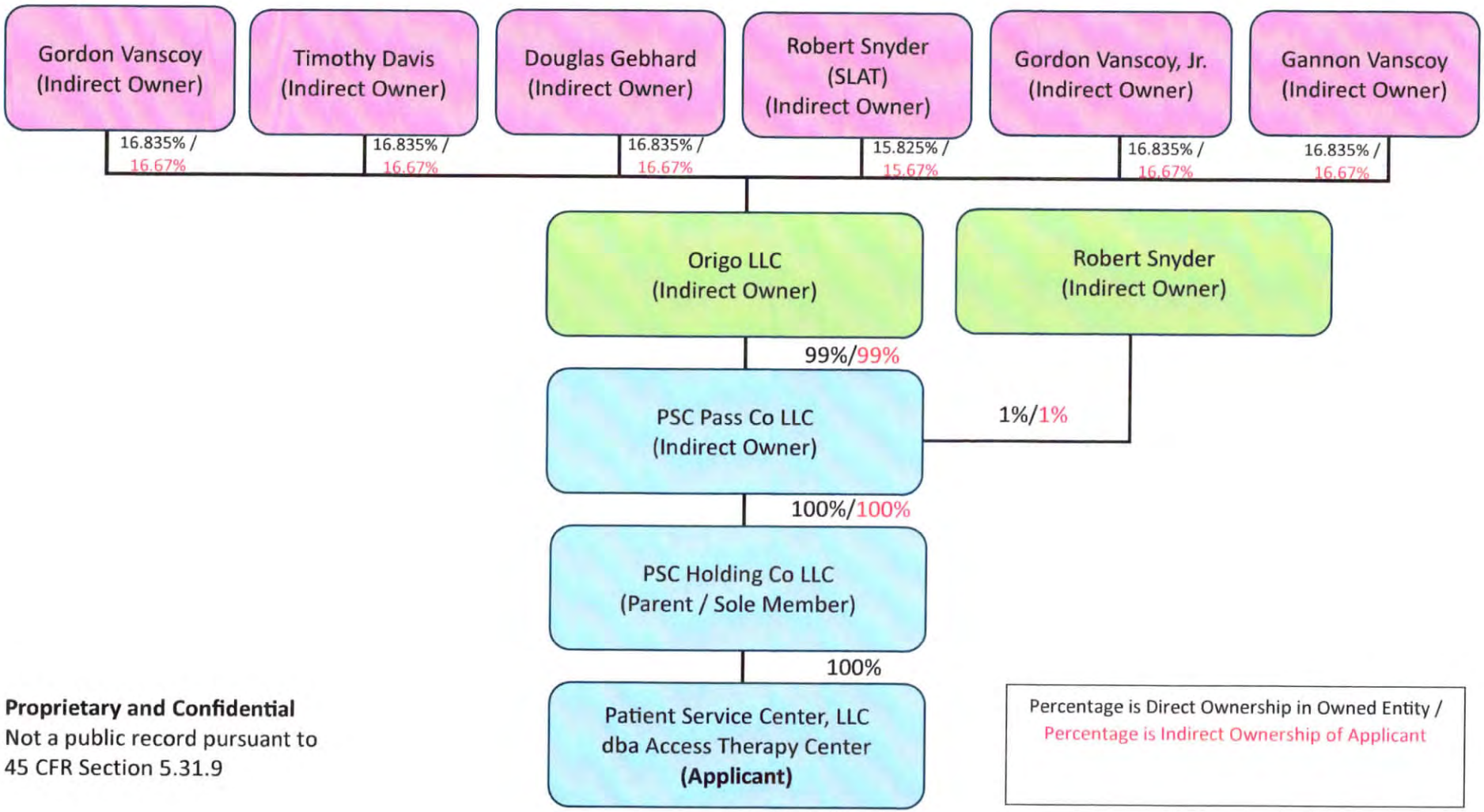
Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
JOHN JAMES COLL	Pharmacist Manager	Pharmacist	RP455047	Active	11/02/2023	09/30/2024

Disciplinary Action Details

No disciplinary actions were found for this license.

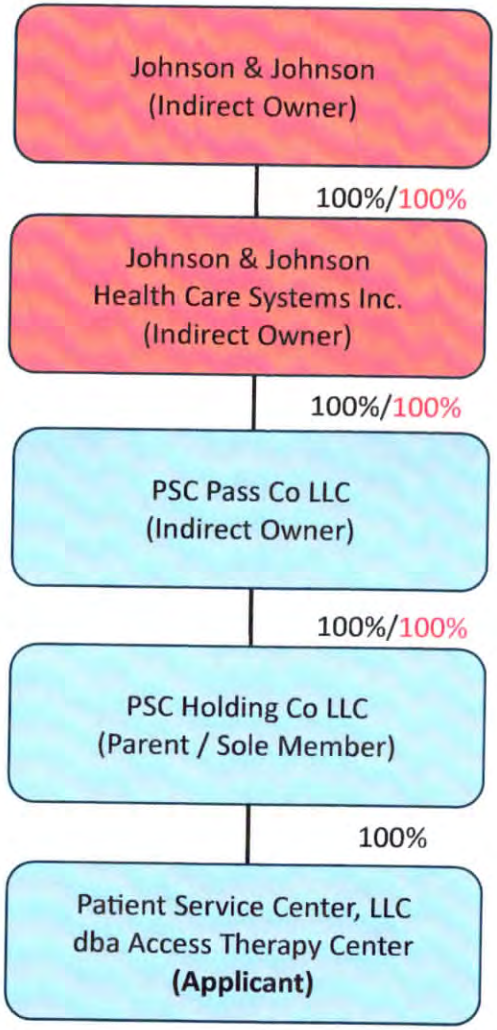
This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

Patient Service Center, LLC dba Access Therapy Center
Pre-Close Organizational Chart



Proprietary and Confidential
Not a public record pursuant to
45 CFR Section 5.31.9

Patient Service Center, LLC dba Access Therapy Center
Post-Close Organizational Chart



Percentage is Direct Ownership in Owned Entity /
Percentage is Indirect Ownership of Applicant

Proprietary and Confidential
Not a public record pursuant to
45 CFR Section 5.31.9

4QQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	☐ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	■ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, S, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	■ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Chewy Pharmacy MCO4, LLC

Physical Address: 3376 NW 35th Avenue Road

City: Ocala State: FL Zip: 34475

Mailing Address (if different from physical address): Same as Physical Address

City: _____ State: _____ Zip: _____

Telephone: 352-820-7412 Toll Free # (NAC 639.708, NRS 639.23286): 877-977-3879

Fax: 866-253-0274 Contact Email: pharmacylicensing@chewy.com

Website: chewy.com/pharmacy

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Razor

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21536

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christopher Razor	NV Pharmacist Registration #: 21536
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Chewy Pharmacy Florida Holding, LLC

Corporation/Organization Name: Chewy Pharmacy MCO4, LLC

Mailing Address: 3376 NW 35th Avenue Road

City: Ocala State: FL Zip: 34475

Telephone: 352-820-7412 Email: pharmacylicensing@chewy.com

Contact Person Name: Christopher Razor

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for Chewy Pharmacy MCO4, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Christopher Razor

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/27/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Christopher Razor hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for Chewy Pharmacy MCO4, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 27rd day of JUNE, 2024

Daniel Liam Murdaugh
Notary Public

DANIEL LIAM MURDAUGH
Notary Public - State of Florida
Commission # HH 505302
My Comm. Expires Mar 18, 2028

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brent Yoder - Vice President

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Brent Yoder

Original signature of Authorized Person (copies or stamps not accepted)

6/27/2024

Date

Board Use Only	Date Received: 7/15/24	Amount: 500.00

Chewy Pharmacy MCO4, LLC Officer List

Name	Title/ Percent of Ownership	Business Address	Business Phone	DOB	SSN
Ornel Cotera	President, 0%	7700 West Sunrise Blvd, Plantation, Fl. 33322	877-977-3879	[redacted]	
Brent Yoder	Vice President, 0%	2506 Boylston Court, Zionsville, IN, 46077	786-320-7111	[redacted]	

State of Florida
Department of State

I certify from the records of this office that CHEWY PHARMACY MCO4, LLC is a Delaware limited liability company authorized to transact business in the State of Florida, qualified on July 11, 2023.

The document number of this limited liability company is M23000008968.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023 and that its status is active.

I further certify that said limited liability company has not filed a Certificate of Withdrawal.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-fifth day of March, 2024

Secretary of State

Tracking Number: 0009927502CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

State of Delaware
Secretary of State
Division of Corporations
Delivered 03:31 PM 06/22/2023
FILED 03:31 PM 06/22/2023
SR 20232829623 - File Number 7529372

STATE OF DELAWARE

CERTIFICATE OF FORMATION

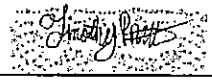
OF LIMITED LIABILITY COMPANY

The undersigned authorized person, desiring to form a limited liability company pursuant to the Limited Liability Company Act of the State of Delaware, hereby certifies as follows:

FIRST: The name of the limited liability company is Chewy Pharmacy MCO4, LLC.

SECOND: The Registered Office of the limited liability company in the State of Delaware is located at 3411 Silverside Road, Tatnall Building No. 104, in the City of Wilmington, Zip Code 19810. The name of the Registered Agent at such address upon whom process against this limited liability company may be served is Corporate Creations Network Inc.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation this 22nd day of June, 2023.



Tim Pratts, Authorized Person

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 29483
Insp # 195530

NAME	PERMIT NUMBER	DATE OF INSPECTION
Chewy Pharmacy MCO4, LLC	34831	05/02/2024
DOING BUSINESS AS		
CHEWY PHARMACY MCO4, LLC		
STREET ADDRESS	**TELEPHONE #**	**EXT**
3376 NW 35th Avenue Road	786-320-7111	
CITY	**COUNTY**	**STATE/ZIP**
OCALA	MARION	FL/34475

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 7:30 am to 6 pm
Monday Y	Monday Hours 7:30 am to 6 pm
Tuesday Y	Tuesday Hours 7:30 am to 6 pm
Wednesday Y	Wednesday Hours 7:30 am to 6 pm
Thursday Y	Thursday Hours 7:30 am to 6 pm
Friday Y	Friday Hours 7:30 am to 6 pm
Saturday Y	Saturday Hours 7:30 am to 6 pm
Sunday Y	Sunday Hours 7:30 am to 6 pm

Registered Pharmacist / Intern / Tech

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # N/A	

License Relations

Pharmacy Tech Training to Pharmacy

CHEWY PHARMACY MCO4, LLC	License # 1408

RX DPT MGR/COR/POR

RAZOR, CHRISTOPHER JAMES	License # 63678

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	No
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes

INV359 - Community Requirements

Insp # 195530

Chewy Pharmacy MCO4, LLC

File # 29483

Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.]	N/A
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	N/A
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	N/A
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.] *Cardinal Health*	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11]	N/A
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	N/A
Controlled substance records and prescription information in computer system are retrieveble and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	N/A
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	N/A

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes
Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for e minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	

If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	Yes
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	Yes
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	Yes

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

SMITH, BOBBY T

Date:5/2/2024

Representative:

Christopher Razor

Date:5/2/2024

Your license number is PH 34831.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
NOVEMBER 15, 2023	**PH 34831**	**142702**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Internet

EXPIRATION DATE: **FEBRUARY 28, 2025**

CHEWY PHARMACY MCO4, LLC
Chewy Pharmacy MCO4, LLC
3376 NW 35TH AVENUE ROAD
OCALA, FL - 34475

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
NOVEMBER 15, 2023	**PH 34831**	**142702**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

CHEWY PHARMACY MCO4, LLC
Chewy Pharmacy MCO4,

Expiration Date: **FEBRUARY 28, 2025**

REGISTRANT SIGNATURE

Department of Health

Chewy Pharmacy MCO4, LLC Chewy Pharmacy MCO4, LLC

License Number: PH34831

Data As Of 7/8/2024

Profession	Pharmacy
License	PH34831
License Status	CLEAR/
Qualifications	Internet
License Expiration Date	2/28/2025
License Original Issue Date	11/14/2023
Address of Record	3376 NW 35th Avenue Road OCALA, FL 34475
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
RAZOR, CHRISTOPHER JAMES	RX DPT MGR/COR/POR	PHARMACIST	63678	11/14/2023

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Chewy Pharmacy MCO4, LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 3376 NW 35th Avenue Road

City: Ocala State: FL Zip: 34475

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 352-820-7412 Website: chewy.com/pharmacy

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Christopher Middle: Last: Razor

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]48th Avenue, Unit 817

City: Ocala State: FL Zip: 34475

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Purdue University College of Pharmacy		08/01-05/07	
Address	**City**	**State**	**Zip**
575 Stadium Mall Drive	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Blue River Valley Jr./Sr. High School		08/97-05/01	
Address	**City**	**State**	**Zip**
4741 Viking Trail	New Castle	IN	47362
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/23-Present	[redacted] SW 48th Ave, Unit 817	Ocala	FL	34474
06/10-12/23	[redacted] Bromwell Ct	Louisville	KY	40245

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Chewy Pharmacy MCO4, LLC			09/23-Present
Business Address	**City**	**State**	**Zip**
3376 NW 35th Avenue Road	Ocala	FL	34475
Phone	**Title**		**Number of Employed Hours**
877-977-3879	Pharmacist in Charge		1440
Description of Duties			
Pharmacist in charge			

Business Name			From - To (MM/YY – MM/YY)
Chewy Wholesale, LLC			03/20-09/23
Business Address	**City**	**State**	**Zip**
11403 Bluegrass Parkway, Suite 675	Louisville	KY	40299
Phone	**Title**		**Number of Employed Hours**
877-977-3879	Designated Representative		6720
Description of Duties			
Designated Representative			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Christopher Razor, **certify that as the designated representative for**

Chewy Pharmacy MCO4, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CJR I am at least 21 years of age;
3. CJR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CJR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CJR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CJR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CJR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Razor

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/27/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Razor

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/27/2024

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of MARION

I, CHRISTOPHER J RAZOR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/27/2024

Date

Subscribed and Sworn to before me this 27TH day of JUNE 2024.

Daniel Liam Murdaugh

Notary Public Signature

DANIEL LIAM MURDAUGH
Notary Public - State of Florida
Commission # HH 505302
My Comm. Expires Mar 18, 2028

(Seal)

APPLICATION FOR CERTIFICATION AS A PROVIDER OF INTERNET PHARMACY SERVICES

Addendum to Pharmacy Application
(Only required if providing internet services)

GENERAL INFORMATION

Name of Nevada license pharmacy: Chewy Pharmacy MCO4, LLC

Nevada license number: N/A - Initial license application

Websites in use or intended to be used: chewy.com/pharmacy

Affiliated websites (websites that link to or otherwise direct users to your website):
N/A

VIPPS CERTIFICATION

Is the pharmacy VIPPS (Verified Internet Pharmacy Practice Sites administered be NABP) certified? Please provide a copy with application. Yes ☑ No ☐

If yes, please sign and date page 3 and you will not need to answer questions 1 through 8.

PHARMACIES LACKING VIPPS CERTIFICATION

1. Is the pharmacy licensed in each state in which the pharmacy will practice pharmacy Yes ☑ No ☐

PLEASE ATTACH A SEPARATE SHEET LISTING ALL THE STATES IN WHICH YOU ARE LICENSED, INCLUDING THE DATE OF INITIAL LICENSURE AND THE LICENSE NUMBER.

2. Does the pharmacy maintain and enforce policies and procedures that ensure the following:

A) That the pharmacy will establish the authenticity of each prescription that the pharmacy receives? Yes ☑ No ☐

B) That the pharmacy will not fill any prescription which has been previously filled by another pharmacy? Yes ☑ No ☐

C) That for each pharmacy the pharmacy fills the prescription cannot be filled by another pharmacy? Yes ☑ No ☐

D) That the pharmacy will authenticate the identity of each patient and prescribing practitioner? Yes ☑ No ☐

E) That the prescriptions will be filled in compliance with all applicable federal and state laws? Yes ☑ No ☐

F) That a patient or the caregiver of the patient may make a complaint to the pharmacy regarding a prescription? Yes ☑ No ☐

G) That if a complaint is made, the complaint will be investigated thoroughly and that the results of the investigation will be communicated to the patient or caregiver? Yes ☑ No ☐

H) That if the investigation of a complaint reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action was taken by the pharmacy? Yes ☑ No ☐

I) That the pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device? Yes ☑ No ☐

J) That the pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices? Yes ☑ No ☐

3. Does the pharmacy obtain and maintain patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes? Yes ☑ No ☐

4. Will the pharmacy provide review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides? Yes ☑ No ☐

5. Does the pharmacy maintain controls of its computer system, information concerning patients, and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents? Yes ☑ No ☐

6. Does the pharmacy comply with applicable federal and state laws regarding the following:

   A) To the dispensing of prescription drugs? Yes ☑ No ☐

   B) To the record keeping related to the patients served by the pharmacy, the purchase of prescription drugs and the sale and dispensing of prescription drugs? Yes ☑ No ☐

   C) To the sale of over-the-counter products, including any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs ? Yes ☑ No ☐

7. Does the pharmacy ship prescriptions to a patient using secure and traceable means? Yes ☑ No ☐

8. Does the pharmacy ship prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopoeia, 25th* edition, 2002, which is hereby adopted by reference? Yes ☑ No ☐

PLEASE ATTACH A COPY OF YOUR POLICIES AND PROCEDURES.

The signature below certifies that the answers provided in this application are true, correct and complete.

Brent E Yoder
Signature of Owner

6/27/2024
Date



Chewy Pharmacy MCO4, LLC is not eligible for the digital pharmacy accreditation because we are veterinary only.

Chewy Pharmacy MCO4, LLC_Licensed States

State	Type	License/Permit #	Effective Date	Expiration Date
Alabama	Non-Resident Pharmacy	115271	3/27/2024	12/31/2024
Arizona	Pharmacy - Limited Service	Y009799	4/19/2024	10/31/2025
Colorado	Prescription Drug Outlet-Out-of-State	OSP.0007926	4/19/2024	10/31/2024
Florida	Internet Pharmacy Licenses	PH34831	11/15/2023	2/28/2025
Georgia	Non-Resident Pharmacy	PHNR002580	4/22/2024	6/30/2025
Kentucky	Non-Resident Pharmacy	FL3077	5/9/2024	6/30/2025
Louisiana	Pharmacy - Nonresident	PHY.008788-NR	2/23/2024	12/31/2024
Mississippi	Non-Resident Pharmacy	18627 / 7.1	2/8/2024	12/31/2025
Montana	Non-Resident Mail Order Pharmacy	PHA-MOP-LIC-105670	6/11/2024	11/30/2024
New Mexico	Non-Resident Pharmacy	PH00005762	4/12/2024	12/31/2025
New York	Non-Resident Pharmacy	040941	4/16/2024	3/31/2027
North Carolina	Pharmacy or Drug Store	15487	6/5/2024	12/31/2024
Ohio	Terminal - Non-Resident Pharmacy - Category 2	240000394	4/8/2024	3/31/2025
Pennsylvania	Non-Resident Pharmacy	NP002159	4/11/2024	8/31/2025
South Carolina	Non-Resident Pharmacy	PY .22362 PNP	5/9/2024	6/30/2025
South Dakota	Non-Resident Pharmacy	400-2441	5/31/2024	6/30/2025
Tennessee	Pharmacy	00007764	4/29/2024	4/30/2026
Texas	Non-Resident CLASS E Pharmacy	35359	5/22/2024	5/31/2026
Wyoming	Non-Resident Retail Pharmacy	NR-52371	5/9/2024	6/30/2025

Chewy Pharmacy	
UNDUE DELAYS	Original Date: July 2018
Document Control Number: 11.0	Revision Date: October 2023

11.0 POLICY

Chewy Pharmacy will have a process for contacting the Pet-Parent and, if necessary, the veterinarian, for any undue delays when trying to dispense and deliver a prescription to the Pet-Parent. This policy will address the definition of an "undue delay", when to activate the policy, and identify whether this delay will affect the care of the companion animal. It will also address how to contact the Pet-Parent, a contingency plan to contact the veterinarian if the Pet-Parent cannot be reached, and when to contact veterinarians for an alternative therapy or filling the medication at a different pharmacy.

11.1 DEFINITIONS

Undue Delay: The inability to provide the prescription(s) to the Pet-Parent in a timely manner (7-10 days) within the normal operating time frame of the pharmacy for filling and dispensing prescriptions.

This can be caused by:

1. A drug on backorder
2. An order that has not received authorization after one week.
3. A carrier that has not delivered the drug within five days of the order being shipped.

11.2 RESPONSIBILITIES

Pharmacists and technicians will be responsible for activating the procedures of this policy when an Undue Delay is encountered. The PIC will ensure that all pharmacy staff employees understand what circumstances will activate this policy.

11.3 PROCEDURES

In the event of an Undue Delay, the following actions will be taken:

1. A pharmacist will review the reason for the Undue Delay and then assess the patient's profile.
2. If the companion animal's health care will be affected, the pharmacist will contact the Pet-Parent to advise of the delay and to inquire what course of action the Pet-Parent may take such as: contacting the prescribing veterinarian, canceling the prescription, obtaining the drug from another source, coordinating with pet-parent and prescriber to arrange for prescription to be filled a pet-parent's local pharmacy of choice as appropriate, or waiting until the drug is available.
3. The pharmacist will document the resolution in the patient's profile comment section for that prescription.

If the mail carrier is the source of the delay, a pharmacy technician will track the shipment by the order's tracking number to determine its status. If the shipment has not yet been delivered and patient requires interim dosage until mailed prescription drug(s) become(s) available, pharmacy staff will contact the pet-parent and recommend that they go to their veterinarian of choice and obtain a sufficient supply of medication to last until the medication is delivered. If the shipment has been delivered to the wrong address, pharmacy staff will contact the carrier and request that the shipment be retrieved and delivered to the correct address. If the shipment is unable to be retrieved, then Chewy Pharmacy will file a report with the carrier and will resend the order at no additional cost to the Pet-Parent.

11.6 TRAINING

The PIC will provide training to the pharmacy staff by going over the policy and answering questions about certain situations.

Chewy Pharmacy	
STORAGE AND SHIPMENT	Original Date: July 2018
Document Control Number: 14.0	Revision Date: October 2023

14.0 POLICY

Chewy Pharmacy will have guidelines for proper storage and shipment of drugs. Storage temperature ranges will be identified and maintained as established by the United States Pharmacopoeia (USP). Contingency plans will be established should the temperatures fall outside of the range.

14.1 DEFINITIONS

Storage Temperature: The manufacturer's recommended temperature for storage of the drug.

14.2 RESPONSIBILITIES

The PIC will be responsible for maintaining the proper temperature in the pharmacy as well as the proper temperature in the refrigerator and freezer.

Pharmacists and technicians will help the PIC by aiding in monitoring the temperatures periodically.

14.3 PROCEDURES

In accordance with USP standards, Chewy Pharmacy will maintain a pharmacy temperature of 68 - 77°F and humidity level less than 40 percent. Digital alerts are sent via email or text message if temperature excursions occur. Temperature and humidity are monitored by a thermo data-logger that monitors and stores data in 15-minute increments. The refrigerator temperature is kept between 36-46°F and is monitored by a thermo data-logger that monitors and stores data in 15-minute increments. The freezer will have a temperature ranging between -20 to -10°C or -4 to 14°F. Currently, Chewy Pharmacy does not have any items that are monitored in the freezer. If a temperature excursion occurs or is expected, all possible methods will be used to prevent the excursion.

If a temperature excursion still occurs, the PIC will attempt to verify drug integrity through professional judgment or contacting the manufacturer. If drug integrity cannot be guaranteed, then the drugs will be disposed of, and the stock replenished.

A daily log will be maintained for monitoring these variables. The log will contain the date and time of monitoring and the results as well as the as the initials of the pharmacist/technician checking.

Factors in determining if a drug's effectiveness has been compromised include the following:

1. Is the drug discolored?
2. If it is a solution, are there particles floating in it?
3. Is the drug sensitive to temperature fluctuation?
4. Was the drug outside the allowable temperature range as determined by USP standards or the prescription label for a significant period of time?
5. Was the drug exposed to excessive humidity?

The PIC will make the final decision to destroy or return a drug to the wholesaler or manufacturer using professional judgment and in consultation with professional resources as needed.

Shipment of medications will be done through a common carrier as appropriate. Packaging and shipping of medications will be conducted by a pharmacist or pharmacy technician and will be conducted in the pharmacy. Protective packaging will be used to ensure drug integrity and, when necessary, Styrofoam coolers and icepacks that have been tested to comply with USP standards and/or specific drug labeling requirements will be used to keep items at refrigerator temperatures. Packaging will be non-descript and tamper evident to help deter inappropriate handling.

Items that must be shipped cold will be sent as express shipments to ensure delays are prevented as much as possible. Any shipment with questionable integrity will be replaced and the adulterated drug will be disposed of.

Test shipments with thermometers and freeze indicators will be sent as deemed appropriate by the PIC. Any time test shipments are performed, the date will be written/typed and saved for two years.

14.4 TRAINING

The PIC will train the staff in proper measuring and recording techniques.

14.5 REVIEW

The PIC will review this policy annually and update it as needed, including but not limited to, any required modifications to temperature control based on updates to the USP standards.

14.6 REFERENCES

USP 40 - General Notices and Requirements (official from May 1, 2017)

USP 40 - Chapter 659 - Packaging and Storage Requirements (official from May 1, 2017)
USP 40 - Chapter 1079 - Good Storage and Distribution Practices for Drug Products (official from May 1, 2017)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Chewy Pharmacy MCO4, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 3376 NW 35th Avenue Road

City: Ocala State: FL Zip: 34475

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 352-820-7412 Website: chewy.com/pharmacy

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Ornel Middle: Last: Cotera

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] West Sunrise Blvd.

City: Plantation State: FL Zip: 33322

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mast Academy		06/96 - 05/00	
Address	**City**	**State**	**Zip**
3979 Rickenbacker Causeway	Miami	FL	33149
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Florida		06/00 - 08/06	
Address	**City**	**State**	**Zip**
205 Fletcher Drive	Gainesville	FL	32611
Diploma/Degree obtained, if any			
B.S Economics			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19 - Current	[redacted] SE 12th Ave.	Deerfield	FL	33441
10/09 - 05/19	[redacted] SE 11th Ave.	Deerfield	FL	33441
03/11 - 11/14	[redacted] Sutton Drive	Matawan	NJ	07747

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Chewy, Inc.			09/15 - Current
Business Address	**City**	**State**	**Zip**
7700 W Sunrise Blvd.	Plantation	FL	33322
Phone	**Title**		
786-320-7111	President, Category Management		
Description of Duties			
Monitor & oversee Chewy Pharmacy, Compounding, OTC, F&T and the practice hub business teams.			

Business Name			From - To (MM/YY – MM/YY)
Office Dept			11/14 - 09/15
Business Address	**City**	**State**	**Zip**
6600 N. Military Trail	Boca Raton	FL	33487
Phone	**Title**		
561-438-4800	Sr. Category Manager		
Description of Duties			
Managed assortment for digital storage category.			

Business Name			From - To (MM/YY – MM/YY)
Hess Corp.			06/07 - 11/14
Business Address	**City**	**State**	**Zip**
1 Hess Plaza	Woodbridge	NJ	07095
Phone	**Title**		
732-750-6888	Category Manager		
Description of Duties			
Managed store assortment for convenience stores.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ornel Cotera

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/2/24

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, ORNEL Cotera, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/2/24

Date

Subscribed and Sworn to before me this 2nd day of July 2024.

Peralta

Notary Public Signature

STACY PERALTA
Notary Public - State of Florida
Commission # HH 488949
My Comm. Expires Feb 5, 2028
Bonded through National Notary Assn.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Chewy Pharmacy MCO4, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 3376 NW 35th Avenue Road

City: Ocala State: FL Zip: 34475

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 352-820-7412 Website: chewy.com/pharmacy

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Brent Middle: Edward Last: Yoder

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addres: [redacted] Boylston Court

City: Zionsville State: IN Zip: 46077

Telephone: [redacted] Email: byoder@chewy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Massachusetts Institute of Technology			06/11-05/13
Address	**City**	**State**	**Zip**
1 Amherst St	Cambridge	MA	02142
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name			From - To (MM/YY – MM/YY)
Massachusetts Institute of Technology			06/11-05/13
Address	**City**	**State**	**Zip**
1 Amherst St	Cambridge	MA	02142
Diploma/Degree obtained, if any			
Masters of Systems Engineering			

School Name			From - To (MM/YY – MM/YY)
Georgia Institute of Technology			08/99-05/04
Address	**City**	**State**	**Zip**
311 Ferst Drive	Atlanta	GA	30332
Diploma/Degree obtained, if any			
BS Industrial Engineering			

School Name			From - To (MM/YY – MM/YY)
Crete-Monee High School			08/95-05/99
Address	**City**	**State**	**Zip**
1515 W Exchange St	Crete	IL	60417
Diploma/Degree obtained, if any			
HS Diploma			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2015-06/2024	[redacted] Boylston Ct	Zionsville	IN	46077
06/2013-03/2015	[redacted] Mallard View Ln	Indianapolis	IN	46226
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Chewy Pharmacy DFW8, LLC			03/23 - Current	
Business Address		**City**	**State**	**Zip**
7243 Grady Niblo Road, Suite 100		Dallas	TX	75236
Phone	**Title**			
469-554-7870	Vice President			
Description of Duties				
Vice President				

Business Name			From - To (MM/YY – MM/YY)	
Chewy Wholesale DFW5, LLC			03/23 - Current	
Business Address		**City**	**State**	**Zip**
7243 Grady Niblo Road, Suite 110		Dallas	TX	75236
Phone	**Title**			
469-554-7840	Vice President			
Description of Duties				
Vice President				

Business Name			From - To (MM/YY – MM/YY)	
Chewy Pharmacy MCO4, LLC			06/23 - Current	
Business Address		**City**	**State**	**Zip**
3376 NW 35th Avenue Road		Ocala	FL	34475
Phone	**Title**			
352-820-7412	Vice President			
Description of Duties				
Vice President				

Business Name			From - To (MM/YY – MM/YY)	
Chewy.com			10/22-06/23	
Business Address		**City**	**State**	**Zip**
1974 Innovation Blvd		Clayton	IN	46118
Phone	**Title**			
317-539-8549	Sr. Director, Pharmacy Operations			
Description of Duties				
Operational director responsible for the fulfillment operations of pharmacy orders				

Business Name			From - To (MM/YY – MM/YY)	
Chewy.com			02/21-10/22	
Business Address		**City**	**State**	**Zip**
1974 Innovation Blvd		Clayton	IN	46118
Phone	**Title**			
317-539-8549	Sr. Director, FC Design and Infrastructure			
Description of Duties				
Responsible for the design, installation, and maintenance of Chewy.com fulfillment assets.				

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Business Name			From - To (MM/YY – MM/YY)	
Chewy.com			3/20-2/21	
Business Address		**City**	**State**	**Zip**
1974 Innovation Blvd.		Clayton	IN	46118
Phone	**Title**			
317-539-8549	Sr. Director, FC Quality, Customer Experience, and Learning and Development			
Description of Duties				
Responsible for fulfillment network quality, SOX compliance, and customer experience. Additionally responsible for developing and executing learning programs for exempt and non exempt employees.				

Business Name			From - To (MM/YY – MM/YY)	
Amazon.com			1/17-2/19	
Business Address		**City**	**State**	**Zip**
4255 Anson Blvd		Whitestown	IN	46075
Phone	**Title**			
317-769-8011	Director, Reliability and Maintenance Engineering			
Description of Duties				
Responsible for the support and maintenance of mechanical, pneumatic, and electrical assets in North, Central, and South America.				

Business Name			From - To (MM/YY – MM/YY)	
Amazon.com			01/17-02/19	
Business Address		**City**	**State**	**Zip**
4255 Anson Blvd		Whitestown	IN	46075
Phone	**Title**			
317-769-8011	Regional Operations Director			
Description of Duties				
Responsible for the fulfillment activities for Amazon.com orders from six warehouses in IN, VA, TN, KY.				

Business Name			From - To (MM/YY – MM/YY)	
Amazon.com			01/15-01/17	
Business Address		**City**	**State**	**Zip**
4255 Anson Blvd		Whitestown	IN	46075
Phone	**Title**			
317-769-8011	Director of Operations			
Description of Duties				
Responsible for the fulfillment activities for Amazon.com orders from a single warehouse in Whitestown, IN.				

Business Name			From - To (MM/YY – MM/YY)	
Amazon.com			01/14-01/15	
Business Address		**City**	**State**	**Zip**
4255 Anson Blvd		Whitestown	IN	46075
Phone	**Title**			
317-769-8011	Sr. Operations Manager			
Description of Duties				
Responsible for outbound shipping activities for Amazon.com orders from a single warehouse in Whitestown, IN				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brent Yoder

Print Name (First, Last)

B. + E. Yoder — 6/27/2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hamilton

I, BRENT YODER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

B. + E Yoder — 6/27/2024

Original Signature — **Date**

Subscribed and Sworn to before me this 27th day of June, 2024.

Paul H Sloan III

Notary Public Signature

PAUL H SLOAN, III
Notary Public - Seal
Boone County - State of Indiana
Commission Number NP0672999
My Commission Expires Sep 15, 2031
(Seal)

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☑ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☑ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Chewy Pharmacy DFW8, LLC

Physical Address: 7243 Grady Niblo Road, Suite 100

City: Dallas State: TX Zip: 75236

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 469-554-7870 Toll Free # (NAC 639.708, NRS 639.23286): 877-977-3879

Fax: 866-253-0274 Contact Email: pharmacylicensing@chewy.com

Website: chewy.com/pharmacy

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Brian Parker

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24140

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Brian Parker	NV Pharmacist Registration #: 24140
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Chewy Pharmacy DFW8, LLC

Corporation/Organization Name: Chewy Pharmacy DFW8, LLC

Mailing Address: 7700 West Sunrise Blvd.

City: Plantation State: FL Zip: 33322

Telephone: 877-977-3879 Email: pharmacylicensing@chewy.com

Contact Person Name: Magan Wagner

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for Chewy Pharmacy DFW8, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Brian Parker

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/08/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Brian Parker hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for Chewy Pharmacy DFW8, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 8th day of July, 2024

Notary Public

NICHOLAS ALEXANDER GLOYESKE
Notary ID #134876507
My Commission Expires
April 29, 2028

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brent Yoder - Vice President

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Brent E Yoder

Original signature of Authorized Person (copies or stamps not accepted)

6/27/2024

Date

Board Use Only	Date Received: _____	Amount: 5000/CC

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Application for Registration for Chewy Pharmacy DFW8, LLC (file number 805061031), a DELAWARE, USA, Foreign Limited Liability Company (LLC), was filed in this office on May 16, 2023.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on April 17, 2024.

Jane Nelson
Secretary of State

STATE OF DELAWARE

CERTIFICATE OF FORMATION

OF LIMITED LIABILITY COMPANY

The undersigned authorized person, desiring to form a limited liability company pursuant to the Limited Liability Company Act of the State of Delaware, hereby certifies as follows:

FIRST: The name of the limited liability company is Chewy Pharmacy DFW8, LLC, LLC.

SECOND: The Registered Office of the limited liability company in the State of Delaware is located at 3411 Silverside Road, Tatnall Building No. 104, in the City of Wilmington, Zip Code 19810. The name of the Registered Agent at such address upon whom process against this limited liability company may be served is Corporate Creations Network Inc.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation this 30th day of March 2023.

/s/ Tim Pratts

Tim Pratts, Authorized Person

State of Delaware
Secretary of State
Division of Corporations
Delivered 12:42 PM 03/30/2023
FILED 12:42 PM 03/30/2023
SR 20231222370 - File Number 7381575

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *CHEWY PHARMACY DFW8, LLC* **License Number:** *34999*

Class of License: *A*

Inspection Information

Type: *Compliance* **Purpose:** *Licensee Request*

Date: *03/13/2024* **Arrival Time:** *9:00 AM* **Departure Time:** *10:30 AM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Not Applicable*
17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Not Applicable*

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Satisfactory*
34. Notifications	*Satisfactory*
76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean	*Satisfactory*
04. Balance inspection	*Not Inspected*

Comment

Advised to repair or remove balance if inoperable, not in use.

05. Equipment Inspection	*Satisfactory*
07. Security	*Satisfactory*
08. Environment	*Satisfactory*
48. Drugs (procurement, temperature, security, out-of-date, samples)	*Satisfactory*
90. TSBP complaint notification	*Satisfactory*

Controlled Substances

10. Prescriptions separated	*Satisfactory*
24. Theft/Loss	*Satisfactory*

Comment

No theft or loss has occurred.

26. Controlled substance prescription compliance	*Not Applicable*
30. Controlled substance invoices dated/initialed by pharmacist	*Not Applicable*
35. Controlled substance invoices separated	*Not Applicable*
46. Drug distribution	*Satisfactory*
53. Possession of controlled substances	*Not Applicable*
57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Satisfactory*
45. Proper dispensing/labeling	*Satisfactory*
54. Proper prepackaging procedures	*Not Applicable*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Satisfactory*

61. Supervision of supportive personnel	*Satisfactory*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Satisfactory*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Satisfactory*
56. Prescription transfers	*Satisfactory*
67. Written drug information provided	*Satisfactory*
80. Patient counseling	*Satisfactory*
82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*
86. Absence of pharmacist records	*Satisfactory*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Satisfactory*
92. Automated dispensing policy & procedures/SOPs	*Satisfactary*

Non-Sterile Compounding

38. Area for non-sterile compounding	*Not Applicable*
43. Records for non-sterile compounding	*Not Applicable*

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).

Brian Parker

Isaac Gonzalez

TEXAS STATE BOARD OF PHARMACY
1801 CONGRESS AVE STE 13.100
AUSTIN TX 78701

CHEWY PHARMACY DFW8, LLC
7243 GRADY NIBLO RD STE 100
DALLAS TX 75236



This certifies that the pharmacy named below is hereby licensed to operate as a Class **A** pharmacy.

License No. **34999** Expiration Date: **10/31/2025**

Balances: **1**

CHEWY PHARMACY DFW8, LLC
7243 GRADY NIBLO RD STE 100
DALLAS TX 75236



Julie R. Spier, R.Ph.
President

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 34999

CHEWY PHARMACY DFW8, LLC

License Information

License Status Active
License # 34999
Expiration Date 10/31/2025
Date License Issued 10/13/2023

Address

7243 GRADY NIBLO RD STE 100
DALLAS, TX 75236
County DALLAS
Phone (877) 977-3879

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Community Pharmacy
Type of Ownership LLC
Type of Pharmacy Other
# of Hospital beds

Employment Information

Pharmacist in Charge
PARKER, BRIAN LEE

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	No

Translating services (Listed Below If Available)

Spanish
Vietnamese
Other

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 3307782 34999 CHEWYPHARMACYDFW8LLC 2023-10 10-2028.pdf
- 3307782 34999 CHEWYPHARMACYDFW8LLC 2024-03 03-2029.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	No
Ship Prescription Out of State	Yes
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	No
24 Hour Service	No
Closed Door	Yes
Compounding, Office Use	No
Home Delivery	No
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	Yes
In-Patient Medication Orders	No

Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
ARMSTRONG, TAMERA KAY	39628	10/24/2000	07/31/2026	Staff	Active
BEKKER, VLAD	51876	07/30/2012	05/31/2025	Staff	Active
BRIONES, DANIELLE	63045	08/03/2018	12/31/2024	Staff	Active
CADDELL, KELLI NICOLE	67296	08/14/2020	05/31/2026	Staff	Active
CHACKO, SUSAN	64494	04/25/2019	05/31/2025	Staff	Active
EDER, MORGAN DANIELLE	72470	06/29/2023	12/31/2024	Staff	Active
JANNAPUREDDY, KRUPAL	41605	07/07/2003	07/31/2025	Staff	Active
JIANG, HAIPEI	54101	10/10/2013	03/31/2026	Staff	Active
KOSHY, JASON	63453	09/06/2018	01/31/2025	Staff	Active
LA, JENNIFER NGOC	65266	08/08/2019	02/28/2025	Staff	Active
LE, DAT TRONG	51419	06/21/2012	10/31/2025	Staff	Active
LEWIS, ADAM	54311	12/19/2013	10/31/2025	Staff	Active
LO, NIDA	69061	08/12/2021	08/31/2025	Staff	Active
LUU, JENNIFER	50785	09/19/2011	10/31/2024	Staff	Active
MANNING, TYLER CECIL	56933	07/30/2015	03/31/2025	Staff	Active
MAO, GRACE FUNG CHUN	60432	05/04/2017	02/28/2025	Staff	Active
NANCE, CAITLIN WHITNEY	65169	08/01/2019	10/31/2025	Staff	Active
NGUYEN, LUCY	72906	08/10/2023	10/31/2025	Staff	Active
NGUYEN-PARKER, TANYA KIM THUONG	65521	08/22/2019	07/31/2025	Staff	Active
OHYE, NOREEN	72765	08/03/2023	01/31/2026	Staff	Active

Page 1 of 2 20 View 1 - 20 of 27

Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
ADEBESO, SOFIAT ABIDEMI	372531	06/19/2024	06/30/2026	Staff	Active
ALEXANDER, FRITZI	361282	09/29/2023	05/31/2026	Staff	Active
BLACKMON, VICTORIA LOUISE	205592	02/09/2012	03/31/2026	Staff	Active
CAMACHO, ALEXANDRA	358965	08/15/2023	08/31/2025	Staff	Active
CAMPOZANO, SAVANNAH NICOLETTE	343454	08/23/2022	07/31/2025	Staff	Active
CANO, RALPH	105965	03/30/2004	09/30/2025	Staff	Active
COLEMAN, APRIL LAWANNA	188355	02/18/2011	11/30/2024	Staff	Active
DAVIS, TONIA	366498	01/30/2024	01/31/2026	Staff	Active
DEVOL, DAMIEN ERIK	357109	07/03/2023	07/31/2025	Staff	Active
ERVIN, ELANTRA DEMARNAE	362539	10/29/2023	10/31/2025	Staff	Active
FLORES, CHRISTOPHER	361959	10/17/2023	10/31/2025	Staff	Active
GARCIA, NANCY	249026	10/28/2015	10/31/2025	Staff	Active
HARVEY, CHARLES	340611	06/14/2022	05/31/2025	Staff	Active
IPINA, DIANA GUADALUPE	277037	11/16/2017	03/31/2026	Staff	Active
JOHNSTON, ERIC BRUCE	360418	09/15/2023	09/30/2025	Staff	Active
KELLEMS, JOHN ROBERT	178408	10/09/2009	01/31/2026	Staff	Active
KOENIG, TIFFANY LATOYA	114370	05/12/2004	12/31/2024	Staff	Active
LILLY, ZORIA ZURIEL	304066	01/10/2020	12/31/2025	Staff	Active
MCCLINTOCK, HALLIE	360086	09/08/2023	05/31/2026	Staff	Active
MEUANSOURINHAKOUN, JOANN	361266	09/28/2023	09/30/2025	Staff	Active

Page 1 of 2 20 View 1 - 20 of 34

Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
CHEWY PHARMACY DFW8, LLC	OWNER	,			
YODER, BRENT EDWARD	OFFICER	,			
COTERA, ORNEL ALEXANDER	OFFICER	,			

Page 1 of 1 20 View 1 - 3 of 3

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

Chewy Pharmacy DFW8, LLC

Owner:
Chewy Pharmacy DFW8, LLC
7700 W Sunrise Blvd.
Plantation, FL 33322
100% Ownership

Corporate Officers:

Name	Title/ Percent of Ownership	Business Address
Ornel Cotera	President, 0%	7700 West Sunrise Blvd, Plantation, FL 33322
Brent Yoder	Vice President, 0%	2506 Boylston Court, Zionsville, IN, 46077

APPLICATION FOR CERTIFICATION AS A PROVIDER OF INTERNET PHARMACY SERVICES

Addendum to Pharmacy Application
(Only required if providing internet services)

GENERAL INFORMATION

Name of Nevada license pharmacy: Chewy Pharmacy DFW8, LLC

Nevada license number: N/A - Initial license application

Websites in use or intended to be used: chewy.com/pharmacy

Affiliated websites (websites that link to or otherwise direct users to your website):
N/A

VIPPS CERTIFICATION

Is the pharmacy VIPPS (Verified Internet Pharmacy Practice Sites administered be NABP) certified? Please provide a copy with application. Yes ☑ No ☐

If yes, please sign and date page 3 and you will not need to answer questions 1 through 8.

PHARMACIES LACKING VIPPS CERTIFICATION

1. Is the pharmacy licensed in each state in which the pharmacy will practice pharmacy Yes ☑ No ☐

PLEASE ATTACH A SEPARATE SHEET LISTING ALL THE STATES IN WHICH YOU ARE LICENSED, INCLUDING THE DATE OF INITIAL LICENSURE AND THE LICENSE NUMBER.

2. Does the pharmacy maintain and enforce policies and procedures that ensure the following:

A) That the pharmacy will establish the authenticity of each prescription that the pharmacy receives? Yes ☑ No ☐

B) That the pharmacy will not fill any prescription which has been previously filled by another pharmacy? Yes ☑ No ☐

C) That for each pharmacy the pharmacy fills the prescription cannot be filled by another pharmacy? Yes ☑ No ☐

D) That the pharmacy will authenticate the identity of each patient and prescribing practitioner? Yes ☑ No ☐

E) That the prescriptions will be filled in compliance with all applicable federal and state laws? Yes ☑ No ☐

F) That a patient or the caregiver of the patient may make a complaint to the pharmacy regarding a prescription? Yes ☑ No ☐

G) That if a complaint is made, the complaint will be investigated thoroughly and that the results of the investigation will be communicated to the patient or caregiver? Yes ☑ No ☐

H) That if the investigation of a complaint reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action was taken by the pharmacy? Yes ☑ No ☐

I) That the pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device? Yes ☑ No ☐

J) That the pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices? Yes ☑ No ☐

3. Does the pharmacy obtain and maintain patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes? Yes ☑ No ☐

4. Will the pharmacy provide review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides? Yes ☑ No ☐

5. Does the pharmacy maintain controls of its computer system, information concerning patients, and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents? Yes ☑ No ☐

6. Does the pharmacy comply with applicable federal and state laws regarding the following:

   A) To the dispensing of prescription drugs? Yes ☑ No ☐

   B) To the record keeping related to the patients served by the pharmacy, the purchase of prescription drugs and the sale and dispensing of prescription drugs? Yes ☑ No ☐

   C) To the sale of over-the-counter products, including any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs ? Yes ☑ No ☐

7. Does the pharmacy ship prescriptions to a patient using secure and traceable means? Yes ☑ No ☐

8. Does the pharmacy ship prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopoeia, 25th* edition, 2002, which is hereby adopted by reference? Yes ☑ No ☐

PLEASE ATTACH A COPY OF YOUR POLICIES AND PROCEDURES.

The signature below certifies that the answers provided in this application are true, correct and complete.

Brent E Yoder
Signature of Owner

6/27/2024
Date

Chewy Pharmacy DFW8, LLC_Licensed States

State	Type	License/Permit #	Effective Date	Expiration Date
Alabama	Non-Resident Pharmacy	115282	5/2/2024	12/31/2024
Arizona	Pharmacy - Limited Service	Y009794	4/5/2024	10/31/2025
Colorado	Prescription Drug Outlet-Out-of-State	OSP.0007873	12/14/2023	10/31/2024
Florida	Non-Resident Pharmacy	PH35112	5/1/2024	2/28/2025
Idaho	Nonresident Drug Outlet Registration	NDO75101	4/22/2024	12/31/2024
Indiana	Non-Resident Pharmacy	64003593A	7/11/2024	12/31/2025
Iowa	Non-Resident Pharmacy	5707	3/1/2024	12/31/2024
Kansas	Non-Resident Pharmacy	22-122241	1/31/2024	6/30/2025
Kentucky	Non-Resident Pharmacy	TX3078	5/9/2024	6/30/2025
Louisiana	Pharmacy - Nonresident	PHY.008806-NR	3/26/2024	12/31/2024
Maine	Mail Order Pharmacy	MO40003503	7/12/2024	12/31/2024
Mississippi	Non-Resident Pharmacy	18615 / 7.1	12/18/2023	12/31/2025
Missouri	Non-Resident Pharmacy	2023049431	12/18/2023	10/31/2025
Montana	Mail Order Pharmacy	PHA-MOP-LIC-102529	2/21/2024	11/30/2024
New Mexico	Non-Resident Pharmacy	PH00005746	2/26/2024	12/31/2025
New York	Non-Resident Pharmacy	040925	4/11/2024	3/31/2027
North Dakota	Class G - Out of State	PHAR2116	3/20/2024	6/30/2025
Ohio	Terminal - Non-Resident Pharmacy - Category 2	240000393	4/8/2024	3/31/2025
Oklahoma	Non-Resident Pharmacy	99-9584	11/20/2023	11/30/2024
Oregon	Retail Drug Outlet Registration	RP-0003989	5/31/2024	3/31/2025
Pennsylvania	Non-Resident Pharmacy	NP002158	4/8/2024	8/31/2025
South Dakota	Non-Resident Pharmacy	400-2440	5/13/2024	6/30/2025
Tennessee	Non-Resident Pharmacy	*00007695	12/14/2023	12/31/2025
Texas	Pharmacy	34999	10/13/2023	10/31/2025
Utah	Pharmacy - Class D	13974758-1708	6/26/2024	9/30/2025
Virginia	Non-Resident Pharmacy	214002686	6/27/2024	6/30/2025
Washington	Pharmacy Non-Resident License	PHNR.FO.61560699	7/15/2024	5/31/2025
Wisconsin	Pharmacy	3370-43	7/3/2024	5/31/2026
Wyoming	Non-Resident Retail Pharmacy	NR-52339	2/27/2024	6/30/2025

Chewy Pharmacy	
UNDUE DELAYS	Original Date: July 2018
Document Control Number: 11.0	Revision Date: October 2023

11.0 POLICY

Chewy Pharmacy will have a process for contacting the Pet-Parent and, if necessary, the veterinarian, for any undue delays when trying to dispense and deliver a prescription to the Pet-Parent. This policy will address the definition of an "undue delay", when to activate the policy, and identify whether this delay will affect the care of the companion animal. It will also address how to contact the Pet-Parent, a contingency plan to contact the veterinarian if the Pet-Parent cannot be reached, and when to contact veterinarians for an alternative therapy or filling the medication at a different pharmacy.

11.1 DEFINITIONS

Undue Delay: The inability to provide the prescription(s) to the Pet-Parent in a timely manner (7-10 days) within the normal operating time frame of the pharmacy for filling and dispensing prescriptions.

This can be caused by:

1. A drug on backorder
2. An order that has not received authorization after one week.
3. A carrier that has not delivered the drug within five days of the order being shipped.

11.2 RESPONSIBILITIES

Pharmacists and technicians will be responsible for activating the procedures of this policy when an Undue Delay is encountered. The PIC will ensure that all pharmacy staff employees understand what circumstances will activate this policy.

11.3 PROCEDURES

In the event of an Undue Delay, the following actions will be taken:

1. A pharmacist will review the reason for the Undue Delay and then assess the patient's profile.
2. If the companion animal's health care will be affected, the pharmacist will contact the Pet-Parent to advise of the delay and to inquire what course of action the Pet-Parent may take such as: contacting the prescribing veterinarian, canceling the prescription, obtaining the drug from another source, coordinating with pet-parent and prescriber to arrange for prescription to be filled a pet-parent's local pharmacy of choice as appropriate, or waiting until the drug is available.
3. The pharmacist will document the resolution in the patient's profile comment section for that prescription.

If the mail carrier is the source of the delay, a pharmacy technician will track the shipment by the order's tracking number to determine its status. If the shipment has not yet been delivered and patient requires interim dosage until mailed prescription drug(s) become(s) available, pharmacy staff will contact the pet-parent and recommend that they go to their veterinarian of choice and obtain a sufficient supply of medication to last until the medication is delivered. If the shipment has been delivered to the wrong address, pharmacy staff will contact the carrier and request that the shipment be retrieved and delivered to the correct address. If the shipment is unable to be retrieved, then Chewy Pharmacy will file a report with the carrier and will resend the order at no additional cost to the Pet-Parent.

11.6 TRAINING

The PIC will provide training to the pharmacy staff by going over the policy and answering questions about certain situations.

Chewy Pharmacy	
STORAGE AND SHIPMENT	Original Date: July 2018
Document Control Number: 14.0	Revision Date: October 2023

14.0 POLICY

Chewy Pharmacy will have guidelines for proper storage and shipment of drugs. Storage temperature ranges will be identified and maintained as established by the United States Pharmacopoeia (USP). Contingency plans will be established should the temperatures fall outside of the range.

14.1 DEFINITIONS

Storage Temperature: The manufacturer's recommended temperature for storage of the drug.

14.2 RESPONSIBILITIES

The PIC will be responsible for maintaining the proper temperature in the pharmacy as well as the proper temperature in the refrigerator and freezer.

Pharmacists and technicians will help the PIC by aiding in monitoring the temperatures periodically.

14.3 PROCEDURES

In accordance with USP standards, Chewy Pharmacy will maintain a pharmacy temperature of 68 - 77°F and humidity level less than 40 percent. Digital alerts are sent via email or text message if temperature excursions occur. Temperature and humidity are monitored by a thermo data-logger that monitors and stores data in 15-minute increments. The refrigerator temperature is kept between 36-46°F and is monitored by a thermo data-logger that monitors and stores data in 15-minute increments. The freezer will have a temperature ranging between -20 to -10°C or -4 to 14°F. Currently, Chewy Pharmacy does not have any items that are monitored in the freezer. If a temperature excursion occurs or is expected, all possible methods will be used to prevent the excursion.

If a temperature excursion still occurs, the PIC will attempt to verify drug integrity through professional judgment or contacting the manufacturer. If drug integrity cannot be guaranteed, then the drugs will be disposed of, and the stock replenished.

A daily log will be maintained for monitoring these variables. The log will contain the date and time of monitoring and the results as well as the as the initials of the pharmacist/technician checking.

Factors in determining if a drug's effectiveness has been compromised include the following:

1. Is the drug discolored?
2. If it is a solution, are there particles floating in it?
3. Is the drug sensitive to temperature fluctuation?
4. Was the drug outside the allowable temperature range as determined by USP standards or the prescription label for a significant period of time?
5. Was the drug exposed to excessive humidity?

The PIC will make the final decision to destroy or return a drug to the wholesaler or manufacturer using professional judgment and in consultation with professional resources as needed.

Shipment of medications will be done through a common carrier as appropriate. Packaging and shipping of medications will be conducted by a pharmacist or pharmacy technician and will be conducted in the pharmacy. Protective packaging will be used to ensure drug integrity and, when necessary, Styrofoam coolers and icepacks that have been tested to comply with USP standards and/or specific drug labeling requirements will be used to keep items at refrigerator temperatures. Packaging will be non-descript and tamper evident to help deter inappropriate handling.

Items that must be shipped cold will be sent as express shipments to ensure delays are prevented as much as possible. Any shipment with questionable integrity will be replaced and the adulterated drug will be disposed of.

Test shipments with thermometers and freeze indicators will be sent as deemed appropriate by the PIC. Any time test shipments are performed, the date will be written/typed and saved for two years.

14.4 TRAINING

The PIC will train the staff in proper measuring and recording techniques.

14.5 REVIEW

The PIC will review this policy annually and update it as needed, including but not limited to, any required modifications to temperature control based on updates to the USP standards.

14.6 REFERENCES

USP 40 - General Notices and Requirements (official from May 1, 2017)

USP 40 - Chapter 659 - Packaging and Storage Requirements (official from May 1, 2017)
U5P 40 - Chapter 1079 - Good Storage and Distribution Practices for Drug Products (official from May 1, 2017)



Chewy Pharmacy DFW8, LLC is not eligible for the digital pharmacy accreditation because we are veterinary only.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Chewy Pharmacy DFW8, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 7243 Grady Niblo Road, Suite 100

City: Dallas State: TX Zip: 75236

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 352-820-7412 Website: chewy.com/pharmacy

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Ornel Middle: Last: Cotera

Alias(es, nicknames, name changes, etc.): N/A

Date of Birt[redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] West Sunrise Blvd.

City: Plantation State: FL Zip: 33322

Telephone [redacted] Email: ocotera@chewy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mast Academy		06/96 - 05/00	
Address	**City**	**State**	**Zip**
3979 Rickenbacker Causeway	Miami	FL	33149
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Florida		06/00 - 08/06	
Address	**City**	**State**	**Zip**
205 Fletcher Drive	Gainesville	FL	32611
Diploma/Degree obtained, if any			
B.S Economics			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19 - Current	[redacted] SE 12th Ave.	Deerfield	FL	33441
10/09 - 05/19	[redacted] SE 11th Ave.	Deerfield	FL	33441
03/11 - 11/14	[redacted] Sutton Drive	Matawan	NJ	07747
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Chewy, Inc.			09/15 - Current
Business Address	**City**	**State**	**Zip**
7700 W Sunrise Blvd.	Plantation	FL	33322
Phone	**Title**		
786-320-7111	President, Category Management		
Description of Duties			
Monitor & oversee Chewy Pharmacy, Compounding, OTC, F&T and the practice hub business teams.			

Business Name			From - To (MM/YY – MM/YY)
Office Dept			11/14 - 09/15
Business Address	**City**	**State**	**Zip**
6600 N. Military Trail	Boca Raton	FL	33487
Phone	**Title**		
561-438-4800	Sr. Category Manager		
Description of Duties			
Managed assortment for digital storage category.			

Business Name			From - To (MM/YY – MM/YY)
Hess Corp.			06/07 - 11/14
Business Address	**City**	**State**	**Zip**
1 Hess Plaza	Woodbridge	NJ	07095
Phone	**Title**		
732-750-6888	Category Manager		
Description of Duties			
Managed store assortment for convenience stores.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ornel Cotera

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/2/24

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Ornel Cotera, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/2/24

Date

Subscribed and Sworn to before me this 2nd day of July 2024

Peralta

Notary Public Signature

STACY PERALTA
Notary Public - State of Florida
Commission # HH 488949
My Comm. Expires Feb 5, 2028
Bonded through National Notary Assn.
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Chewy Pharmacy DFW8, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 7243 Grady Niblo Road, Suite 100

City: Dallas State: TX Zip: 75236

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 469-554-7870 Website: chewy.com/pharmacy

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Brent Middle: Edward Last: Yoder

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Boylston Court

City: Zionsville State: IN Zip: 46077

Telephone: [redacted] Email: byoder@chewy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Massachusetts Institute of Technology		06/11-05/13	
Address	**City**	**State**	**Zip**
1 Amherst St	Cambridge	MA	02142
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Massachusetts Institute of Technology		06/11-05/13	
Address	**City**	**State**	**Zip**
1 Amherst St	Cambridge	MA	02142
Diploma/Degree obtained, if any			
Masters of Systems Engineering			

School Name		From - To (MM/YY – MM/YY)	
Georgia Institute of Technology		08/99-05/04	
Address	**City**	**State**	**Zip**
311 Ferst Drive	Atlanta	GA	30332
Diploma/Degree obtained, if any			
BS Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Crete-Monee High School		08/95-05/99	
Address	**City**	**State**	**Zip**
1515 W Exchange St	Crete	IL	60417
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2015-06/2024	[redacted] Boylston Ct	Zionsville	IN	46077
06/2013-03/2015	[redacted] Mallard View Ln	Indianapolis	IN	46226

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Chewy Pharmacy DFW8, LLC			03/23 - Current	
Business Address		**City**	**State**	**Zip**
7243 Grady Niblo Road, Suite 100		Dallas	TX	75236
Phone	**Title**			
469-554-7870	Vice President			
Description of Duties				
Vice President				

Business Name			From - To (MM/YY – MM/YY)	
Chewy Wholesale DFW5, LLC			03/23 - Current	
Business Address		**City**	**State**	**Zip**
7243 Grady Niblo Road, Suite 110		Dallas	TX	75236
Phone	**Title**			
469-554-7840	Vice President			
Description of Duties				
Vice President				

Business Name			From - To (MM/YY – MM/YY)	
Chewy Pharmacy MCO4, LLC			06/23 - Current	
Business Address		**City**	**State**	**Zip**
3376 NW 35th Avenue Road		Ocala	FL	34475
Phone	**Title**			
352-820-7412	Vice President			
Description of Duties				
Vice President				

Business Name			From - To (MM/YY – MM/YY)	
Chewy.com			10/22-06/23	
Business Address		**City**	**State**	**Zip**
1974 Innovation Blvd		Clayton	IN	46118
Phone	**Title**			
317-539-8549	Sr. Director, Pharmacy Operations			
Description of Duties				
Operational director responsible for the fulfillment operations of pharmacy orders				

Business Name			From - To (MM/YY – MM/YY)	
Chewy.com			02/21-10/22	
Business Address		**City**	**State**	**Zip**
1974 Innovation Blvd		Clayton	IN	46118
Phone	**Title**			
317-539-8549	Sr. Director, FC Design and Infrastructure			
Description of Duties				
Responsible for the design, installation, and maintenance of Chewy.com fulfillment assets.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Chewy.com			3/20-2/21
Business Address	**City**	**State**	**Zip**
1974 Innovation Blvd.	Clayton	IN	46118
Phone	**Title**		
317-539-8549	Sr. Director, FC Quality, Customer Experience, and Learning and Development		

Description of Duties

Responsible for fulfillment network quality, SOX compliance, and customer experience. Additionally responsible for developing and executing learning programs for exempt and non exempt employees.

Business Name			From - To (MM/YY – MM/YY)
Amazon.com			1/17-2/19
Business Address	**City**	**State**	**Zip**
4255 Anson Blvd	Whitestown	IN	46075
Phone	**Title**		
317-769-8011	Director, Reliability and Maintenance Engineering		

Description of Duties

Responsible for the support and maintenance of mechanical, pneumatic, and electrical assets in North, Central, and South America.

Business Name			From - To (MM/YY – MM/YY)
Amazon.com			01/17-02/19
Business Address	**City**	**State**	**Zip**
4255 Anson Blvd	Whitestown	IN	46075
Phone	**Title**		
317-769-8011	Regional Operations Director		

Description of Duties

Responsible for the fulfillment activities for Amazon.com orders from six warehouses in IN, VA, TN, KY.

Business Name			From - To (MM/YY – MM/YY)
Amazon.com			01/15-01/17
Business Address	**City**	**State**	**Zip**
4255 Anson Blvd	Whitestown	IN	46075
Phone	**Title**		
317-769-8011	Director of Operations		

Description of Duties

Responsible for the fulfillment activities for Amazon.com orders from a single warehouse in Whitestown, IN.

Business Name			From - To (MM/YY – MM/YY)
Amazon.com			01/14-01/15
Business Address	**City**	**State**	**Zip**
4255 Anson Blvd	Whitestown	IN	46075
Phone	**Title**		
317-769-8011	Sr. Operations Manager		

Description of Duties

Responsible for outbound shipping activities for Amazon.com orders from a single warehouse in Whitestown, IN

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brent Yoder

Print Name (First, Last)

B + E Yoder — 6/27/2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hamilton

I, BRENT YODER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

B + E. Yoder — 6/27/2024

Original Signature — **Date**

Subscribed and Sworn to before me this 27th day of June, 2024.

Paul H Sloan

Notary Public Signature

PAUL H SLOAN, III
Notary Public - Seal
Boone County - State of Indiana
Commission Number NP0672999
My Commission Expires Sep 15, 2031
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Chewy Pharmacy DFW8, LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 7243 Grady Niblo Road, Suite 100

City: Dallas State: TX Zip: 75236

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 469-554-7870 Website: chewy.com/pharmacy

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Brian Middle: Last: Parker

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Tennison Pkwy

City: Colleyville State: TX Zip: 76034

Telephone: [redacted] Email: pharmacylicensing@chewy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Kentucky		08/88 - 05/94	
Address	**City**	**State**	**Zip**
789 S Limestone	Lexington	KY	40506
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Lafayette High School		08/84 - 05/88	
Address	**City**	**State**	**Zip**
401 Reed Lane	Lexington	KY	40503
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/23 - Present	[redacted]Tennison Pkwy	Colleyville	TX	76034
08/23 - 09/23	[redacted]Bluffs Lane, Unit 13213	Grapevine	TX	76051
06/13 - 08/23	[redacted]Glenbrook Road	Louisville	KY	40223
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Chewy Pharmacy DFw8, LLC			05/23 - Present	
Business Address		**City**	**State**	**Zip**
7243 Grady Niblo Road, Suite 100		Dallas	TX	75236
Phone	**Title**		**Number of Employed Hours**	
469-554-7870	Pharmacist in Charge		2240	
Description of Duties				
Pharmacist in Charge of retail mail order pharmacy dispensing medications to pet parents.				

Business Name			From - To (MM/YY – MM/YY)	
Chewy Pharmacy, LLC			08/18 - 05/23	
Business Address		**City**	**State**	**Zip**
11403 Bluegrass Parkway, Suite 650		Jeffersontown	KY	40299
Phone	**Title**		**Number of Employed Hours**	
877-977-3879	Pharmacist Lead		10,400	
Description of Duties				
Managing a group of pharmacist and also personally filling/approving prescriptions for pets in retail mail order pharmacy.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Brian Parker, **certify that as the designated representative for**

Chewy Pharmacy DFW8, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BLP I am at least 21 years of age;
3. BLP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BLP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BLP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BLP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BLP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brian Parker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/08/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian Parker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/08/2024

Date

Please have this section completed in the presence of a Notary Public.

State of TEXAS, ss. County of DALLAS

I, BRIAN LEE PARKER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/08/2024

Date

Subscribed and Sworn to before me this 8th day of July 2024

Notary Public Signature

NICHOLAS ALEXANDER GLOYESKE
Notary ID #134876507
My Commission Expires
April 29, 2028

(Seal)

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: BD9458969 ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Diabetes Supply Center of the Midlands, LLC

Physical Address: 10304 Crown Point Ave

City: Omaha State: Nebraska Zip: 68134

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 402-399-8444 Toll Free # (NAC 639.708, NRS 639.23286): 800-779-3374

Fax: _____ Contact Email: licensing@adapthealth.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Aaron Fredricks

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24156

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Aaron Fredricks	NV Pharmacist Registration #: 24156
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): AdaptHealth, LLC

Corporation Name: AdaptHealth Corp

Mailing Address: 220 W Germantown Pike Ste 250

City: Plymouth Meeting State: Pennsylvania Zip: 19462

Telephone: 610-424-4515 Email: licensing@adapthealth.com

Contact Person Name: Heather O'Neal

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Compliance Officer (title) for Diabetes Supply Center of the Midlands, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Wendy Russalesi

Print Name of Authorized Person

Wendy Russalesi

Original Signature of Authorized Person (copies or stamps not accepted)

5/21/2024

Date

Section 10: Affidavit for Pharmacies: MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Wendy Russalesi hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Compliance Officer (title) for Diabetes Supply Center of the Midlands, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Jennifer M Bagwell
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 21st day of May, 2024

Jennifer M Bagwell
Notary Public

Commonwealth of Pennsylvania - Notary Seal
JENNIFER M. BAGWELL, Notary Public
Montgomery County
My Commission Expires December 13, 2026
Commission Number 1429144

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Wendy Russalesi

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

5/21/2024
Date

Board Use Only	Date Received: 6/25/24	Amount: $500-ck 581673

STATE OF NEBRASKA

United States of America, } ss.
State of Nebraska }

Secretary of State
State Capitol
Lincoln, Nebraska

I, Robert B. Evnen, Secretary of State of the State of Nebraska, do hereby certify that

DIABETES SUPPLY CENTER OF THE MIDLANDS, LLC

was duly formed under the laws of Nebraska on August 27, 2020;

all fees, taxes, and penalties due under the Nebraska Uniform Limited Liability Company Act or other law to the Secretary of State have been paid;

the Company's most recent biennial report required by section 21-125 has been filed by the Secretary of State;

the Secretary of State has not administratively dissolved the company;

the Company has not delivered to the Secretary of State for filing a Statement of Dissolution;

a Statement of Termination has not been filed by the Secretary of State.

This certificate is not to be construed as an endorsement, recommendation, or notice of approval of the entity's financial condition or business activities and practices.

In Testimony Whereof,

I have hereunto set my hand and affixed the Great Seal of the State of Nebraska on this date of

May 13, 2024

Secretary of State

Verification ID 0e22995 has been assigned to this document. Go to ne.gov/go/validate to validate authenticity for up to 12 months.

STATE OF NEBRASKA
DEPARTMENT OF HEALTH & HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
Licensure Unit
P. O. Box 94986
Lincoln, NE 68509-4986

PHARMACY QUALITY ASSURANCE REPORT

Pharmacy License Number: #3234 Exp. Date: 7/1/24

DEA registration Number: BD9458969 Exp. Date: 6/30/26

Owner: Adapt Health, LLC

Pharmacy Name: Diabetes Supply Center of the Midlands, LLC

Pharmacy Street Address: 10304 Crown Point Avenue

Pharmacy City, State, Zip Code Omaha, NE 68134

Pharmacy Telephone #: (402) 399-8444 Pharmacy Fax #: (844) 763-9349

Pharmacy E-mail: afredricks@adapthealth.com

Pharmacy Hours: M-F 9am to 5:30pm

List Pharmacy Personnel:

Name of Pharmacist-In-Charge: Aaron Fredricks RP License #12933

Staff Pharmacists & Interns Name & NE RPh. License # Or NE Intern Registration #	**Pharmacy Technicians Name & NE Registration #**	**Technician Certifying Body, Certification # if applicable, & Certification Expiration Date**
Lisa Bucksbee #10299	Amy Stillwell #1839	PTCB #140109493139456 10/31/24
Vance Wagner #10400	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____#_____	_____#_____	_____#_____ _____
_____	_____	_____

SOFTWARE: Pioneer Rx RX'S PER DAY: ~200

Dean Willson, RP
(Pharmacy Inspector)

10/18/2023
(Date of Inspection

Section Cited	Requirement	C	NC	NA
CFR = 21 CFR Ch.II NAC = Nebraska Administrative Code NRS = Nebraska Revised Statute USC = United States Code USP= United States Pharmacopeia	C = In Compliance NC = Not in Compliance NA = Not Applicable			
175 NAC 8-005	1. All information provided on the current pharmacy license document is correct, including name of facility, ownership, address, and name of pharmacist in charge. If non-compliant, contact the Department at: dhhs.medicaloffice@nebraska.gov	☒	☐	☐
175 NAC 8-007.01 NRS 28-410 CFR 1301.71 CFR 1301.75 CFR 1301.76	2. Adequate security is maintained for the prescription inventory and prescription records.	☒	☐	☐
175 NAC 8-006.02	3. Drugs, devices and biologicals are stored under proper conditions. Storage conditions shall be monitored regularly.	☒	☐	☐
175 NAC 8-008.02	4. The pharmacy is: a. maintained in a clean, orderly, and sanitary manner;	☒	☐	☐
NRS 38-2866	b. open for the practice of pharmacy only when a pharmacist is physically present.	☒	☐	☐
175 NAC 8-008.03	5. The pharmacy maintains in printed or electronic form appropriate reference material for the practice of pharmacy.	☒	☐	☐
175 NAC 8-008.01 USP 795 USP 797	6. The pharmacy provides the pharmacist access to all utilities/equipment needed to practice pharmacy. Water used for compounding is at USP standards. When applicable, water purification systems are maintained.	☒	☐	☐
NRS 38-2869 (2)(a)	7. Patient counseling is being provided as required.	☒	☐	☐
NRS 38-2869 (2)(a)	8. The pharmacy maintains documentation of a patient's refusal of counseling.	☒	☐	☐
NRS 38-2869 (2)(a)	9. Patient counseling is being done by only a pharmacist or pharmacist intern.	☒	☐	☐
NRS 38-2869	10. Prior to the dispensing or the delivery of each new or refill prescription, a pharmacist is conducting a prospective drug utilization review.	☒	☐	☐
NRS 28-414.02 CFR 1304, 1306,1311	11. All computer or electronic record keeping requirements are met including requirements for electronic prescriptions for controlled substances.	☒	☐	☐
CFR 1305 CFR 1311.45 CFR 1311.60	12. Acquisition and distribution requirements for Schedule II controlled substances are met regarding the use of an official order form or the electronic equivalent. Power of Attorney forms completed and filed when applicable.	☒	☐	☐
NRS 28-411(4) CFR 1304.21 CFR 1304.22(c)	13. The pharmacy maintains complete and accurate records of all controlled substances received and/or distributed.	☒	☐	☐

Section Cited	Requirement	C	NC	NA
NRS 28-411 NRS 28-413 NRS 28-414.04 NRS 28-414.05 CFR 1304, 1305,1311,1317	14. The pharmacy complies with all transfer and/or destruction requirements for controlled substances.	☒	☐	☐
21 U.S. Code 351 21 U.S. Code 352 NRS 71-2461 NRS 71-2470	15. The pharmacy does not have in its saleable inventory any drug, device or biological which is misbranded or adulterated, as defined in statute.	☒	☐	☐
NRS 38-28,107	16. The pharmacy assures that all requirements pertaining to unit dose packaging and returned product labeling are met.	☐	☐	☒
NRS 71-2479 NRS 28-414.03	17. The pharmacy assures that all requirements pertaining to multi-drug containers are met, including proper labeling.	☐	☐	☒
NRS 28-410 CFR 1304.11	18. All requirements pertaining to the inventory of controlled substances are met. **Date of Current Inventory: 2/28/23** Copy of annual inventory forwarded to Department within thirty days after completion. Controlled substance inventories require the following Information: 1. **Name** of your facility. 2. **Address** of your facility. 3. **Date and time of day** the inventory was taken. 4. Indicate **open or close** of business. 5. Facility's **DEA#**. 6. **Signature of the Pharmacist-In-Charge**, who is responsible for the inventory. 7. **Schedule II** inventory pages **must be separate** from the **Schedule III, IV, V** inventory pages. 8. **Exact count or measure** of all controlled substances	☒	☐	☐
NRS 28-410(4)	19. All controlled substances are properly stored.	☒	☐	☐
CFR 1306.05 NRS 28-414 NRS 28-414.01 NRS 71-2478	20. All prescriptions contain the required information prior to being filled.	☒	☐	☐
NRS 28-414 NRS 28-414.01 NRS 38-2870(1) CFR 1306.22	21. All refill requirements for prescriptions are in compliance.	☒	☐	☐
CFR 1306.13 CFR 1306.23 NRS 28-414 NRS 28-414.01	22. Partial fillings of controlled substances are recorded and dispensed appropriately.	☒	☐	☐
CFR 1306.05(f) NRS 38-179(13)	23. The pharmacy is not utilizing pre-populated request forms for controlled substance prescriptions.	☒	☐	☐

Section Cited	Requirement	C	NC	NA
CFR 1306.11 NRS 28-414	24. All emergency Schedule II prescription procedures are followed. Only direct verbal authorization from the prescribing practitioner is allowed.	☐	☐	☒
NRS 28-414 NRS 38-2870	25. All requirements for filling electronic prescriptions (e-prescribing) and faxed prescriptions are followed. A manual "wet" signature is required for all paper, including faxed, controlled substance prescriptions.	☒	☐	☐
NRS 28-414.03 NRS 38-2867.01 NRS 71-2479	26. All prescription containers are properly labeled.	☒	☐	☐
NRS 38-28,108 to NRS 38-28,116	27. The pharmacy is in compliance with the Drug Product Selection Act	☒	☐	☐
175 NAC 8-007 NRS 28-414.03 CFR 1304.04 CFR 1311	28. An appropriate filing system for inventories and records is used and maintained.	☒	☐	☐
NRS 71-2412 NRS 71-2413 CFR 1306.11 CFR 1306.21	29. Proper records are maintained for Emergency Drug Box use including: a. receipt upon delivery signed by the Director of Nursing or his/her designee b. proof of use forms. c. a list of emergency box drugs identical to the list on the exterior of the emergency box or the electronic inventory record of the electronic or automated emergency box d. policies and procedures for use of electronic or automated emergency box Controlled substance drugs cannot be removed from the Emergency Drug Box until the pharmacy receives a valid oral, faxed, or written prescription from the practitioner.	☐	☐	☒
NRS 38-2854 NRS 38-2866.01 NRS 38-2890 thru NRS 38-2896 172 NAC 128-006	30. All requirements are met for the utilization of Pharmacists, Pharmacy Technicians and Pharmacist Interns, including: a. pharmacists, pharmacist interns, and pharmacy technicians are identified as such. b. a pharmacist's supervision of pharmacy technicians and/or pharmacist interns does not exceed three people, unless an exception applies. c. all pharmacists, pharmacy technicians, and pharmacist interns currently hold an active corresponding credential with the Department d. all pharmacy technicians hold an active certification (as required). Check credential status at: http://www.nebraska.gov/LISSearch/search.cgi If non-compliant, contact the Department at: dhhs.medicaloffice@nebraska.gov	☒	☐	☐

Section Cited	Requirement	C	NC	NA
175 NAC 8-007.02	31. Pharmacy has written disaster preparedness policies and procedures.	☒	☐	☐
NRS 38-2867.03	32. The pharmacy is compliant with "Pharmaceutical Care Agreement" requirements: a. a copy of the agreement with written protocols is available for review by the Department. b. practice agreements and written protocols must be signed by the practitioner authorized to prescribe independently and participating pharmacists. c. practice agreements and written protocols must be reviewed, signed and dated every two years.	☐	☐	☒
NRS 38-2867.01 USP 795	33. The pharmacy is compliant with USP 795 (non-sterile compounding) including Master Formulation and Compounding Records. The preparation labeling shall include the beyond use date and storage conditions.	☐	☐	☒
NRS 38-2867.01 USP 797	34. The pharmacy is compliant with USP 797 (sterile compounding).	☐	☐	☒
NRS 28-456 NRS 28-457 NRS 28-458 NRS 28-459 CFR 1314	35. The pharmacy is compliant with all State and federal regulations pertaining to the retail sale of scheduled listed chemical products/methamphetamine precursors, including: a. a purchaser signature logbook that displays the warning listed under Section 1001 Title 18, US Code. b. records of training and annual self-certification. c. the name or initials of the seller who sold the product is submitted to the exchange.	☐	☐	☒
NRS 71-7444(2)(d) NRS 71-7454(1)	36. The sale, purchase or trade of a prescription drug for emergency medical reasons or for a practitioner to use for routine office procedures does not exceed five percent of sales as provided in section 71-7454.	☒	☐	☐
NRS 71-7444 (2)(a-h); NRS 71-7454	37. All prescription drugs purchased or received are from entities licensed under the Nebraska Wholesale Drug Distributor Licensing Act, with exceptions in 71-7444 or 71-7454.	☒	☐	☐

STATEMENT OF COMPLIANCE PAGE

For each item not in compliance, please list below (may continue on a separate page if needed):

a) The item number that is not in compliance;
b) Why it is not in compliance;
c) How the deficiency will be corrected; and
d) How long it will take to do so

2023 Random Inspection: Inspection OK

a)

b)

c)

d)

NEBRASKA

Good Life. Great Mission.

DEPT. OF HEALTH AND HUMAN SERVICES

Jim Pillen, Governor

Public Health Licensure Unit
Certification of Licensure

This certificate serves as primary source verification of licensure in the State of Nebraska as of the close of the business day before 6/10/2024.

Name:	Diabetes Supply Center of the Midlands, LLC
Owner:	Adapt Health, LLC
Address:	10304 Crown Point Avenue, Omaha, NE
Type:	Community Pharmacy License
Number:	3234
Status:	Active
Issued:	03/11/2022
Expiration:	07/01/2025

Disciplinary/Non-Disciplinary Information:

No disciplinary/non-disciplinary actions taken against this license.

If you have questions about this information, please contact the Licensure Unit at (402) 471-2115 or DHHS.LicensureUnit@nebraska.gov.

DSCM, LLC
List of Officers & Owners

Name/Title	Address	DOB/SSN
Wendy Russalesi, CCO	[redacted]Sage Rd., Toms River, NJ 08753	[redacted]
Jason Clemens, CFO	[redacted]Linden Ct, Flourtown, PA 19031	[redacted]
Suzanne Foster, CEO	[redacted]Justin Circle, Londonderry, NH 03053	[redacted]

AdaptHealth, LLC- Owner 220 W Germantown Pike Ste 250, Plymouth Meeting, PA 19462
45-5553972 (FEIN) Phone: 610-424-4515

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BD9458969	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-01-2023

DIABETES SUPPLY CENTER OF THE MIDLANDS, LLC
10304 CROWN POINT AVE
OMAHA, NE 681341060

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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Form DEA-223 (9/2016)

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☑ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 03154	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Limited Services	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: F&F Scottsdale, LLC dba GoGoMeds West

Physical Address: 17250 N Hartford Dr, Suite 115

City: Scottsdale State: AZ Zip: 85255

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 602-892-4250 Toll Free # (NAC 639.708, NRS 639.23286): 866-453-6143

Fax: 480-563-3630 Contact Email: ggw.licensing@gogomeds.com

Website: www.gogomeds.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Kristen Meyer

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22949

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kristen Meyer (PIC)	NV Pharmacist Registration #: 22949
Name: Andy Takahata	NV Pharmacist Registration #: 21962
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Arizona

Parent Company (if any): F&F Scottsdale, LLC

Corporation/Organization Name: F&F Scottsdale, LLC

Mailing Address: 17250 N Hartford Dr, Suite 115

City: Scottsdale State: AZ Zip: 85255

Telephone: 602-892-4250 Email: ggw.licensing@gogomeds.com

Contact Person Name: Richelle Aldrich

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President/Member (title) for F&F Scottsdale, LLC dba GoGoMeds West (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Ronald Wayde Ferguson

Print Name of Authorized Person

X _____

Original signature of Authorized Person (copies or stamps not accepted)

4/25/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Ronald Wayde Ferguson hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President/Member (title) for F&F Scottsdale, LLC dba GoGoMeds West (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

x _____
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25th day of April, 20 24

_____
Notary Public

HEATHER JOHNSTON
NOTARY PUBLIC
Kentucky, State At Large
Commission # KYNP45363
My Commission Expires 02/18/2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ronald Wayde Ferguson

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

x _____ 4/25/24

Original signature of Authorized Person (copies or stamps not accepted) Date

Board Use Only	Date Received: 6/7/24	Amount: 500-CC

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

F & F SCOTTSDALE, LLC

ACC file number: 23313515

was incorporated under the laws of the State of Arizona on 12/29/2021, and that, according to the records of the Arizona Corporation Commission, said limited liability company is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **05/01/2024**

Douglas R. Clark, Executive Director

DEMOGRAPHICS

AZ permit# :
Y009734

AZ Permit Exp.Date :
10/31/2025

Business Name :
GoGoMeds West

Address :
17250 N Hartford Dr

Zip :
85255

City :
Scottsdale

State :
AZ

Phone :
(602) 892-4250

Fax :
(480) 563-3630

Email :
ggw.licensing@gogomeds.com

Inspection Date :
06/05/2024

PIC :
Kristen Meyer

Pic License Exp Date :
10/31/2024

DEA # :
Pending

Inspection Reviewed With :
Kristen Meyer

Reviewers License# :
S016834

Inspection type :
Change of Ownership

Inspection Conducted By :
Dennis Waggoner

ACTIVITIES

1	Nonsterile Compounding	☐ YES	☑ NO
2	Nonsterile Hazardous Compounding	☐ YES	☑ NO
3	Sterile Compounding	☐ YES	☑ NO
4	Sterile Hazardous Compounding	☐ YES	☑ NO

Hospital Facility Data

Licensed Beds

DHS License #

PHARMACY DEPARTMENT

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

1	Size/Personnel 3339sqft dispensing space = 53 personnel, 2691sqft data processing space = 42 personnel.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675
2	Shelves	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Design-efficient, safe pharmacy practice	☑ S ☐ C/P ☐ U ☐ N/A	R4-22-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)
4	Counter	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(B); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Aisles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(C); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
6	Consultation area No onsite dispensing to patients.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(D)
7	Enclosed (barrier)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675
8	Entry doors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
9	Lighting	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
10	Temperature controlled/Ventilation	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

11	Working counter barrier	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(H)
12	Receiving/checking area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
13	Opening for Rx receipt when closed	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-610(F)
14	Walls	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
15	Ceilings	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
16	Windows	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
17	Floors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
18	Restroom Two sets of M/W restrooms.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	Sink (hot and cold running water)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
20	Nonsterile compounding area No compounding initially.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-410(E)

SECURITY

1	Controlled substances Locked cabinet.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Pharmacist access	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Additional pharmacy drug storage areas	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Filled Rx medication storage	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)
5	Remote drug storage (hospitals)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-654(D); R4-23-672(C)

PHARMACY LIBRARY

1	Pharmacology or Toxicology reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Therapeutics reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Drug compatibility reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Drug product equivalency reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Sterile products reference	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)

6	Policy and procedure manual-pharmacy operations	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)
7	Policy and procedure manual-technicians	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D)
8	Policy and procedure manual-automation	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-614; R4-23-615; R4-23-616; R4-23-654(D); R4-23-701.02; R4-23-701.04
9	Policy and procedure manual-compounding	☐ S	☐ C/P	☐ U	☑ N/A	R4-23-410; R4-23-670
10	Arizona statutes/rules	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Current antidote/drug interaction information	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
12	Poison Control # displayed	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

PHARMACY EQUIPMENT/FORMS

1	Refrigerator	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Freezer	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Computer-security/data storage	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-408
4	Computer-patient profiles	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-408(B)(3)

5	Computer-single drug usage report	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(4)
6	Computer-pharmacist log book/hard copy print out	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(C)(4)
7	Prescription label	☑ S ☐ C/P ☐ U ☐ N/A	ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C)
8	Federal transfer labels	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
9	Warning labels	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
10	Written patient information	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-402(C)(4); R4-23-402(I)
11	Consultation log	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-402(G)
12	Federal medication guides	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR part 208
13	Hospital IV label	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-658
14	Generic Rx blanks	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-402(A); R4-23-407(D)
15	Immunization administration recordkeeping	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-411(F)

16	Schedule V register	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(2)
17	Methamphetamine precursor sales log	☐ S ☐ C/P ☐ U ☑ N/A	ARS 32-1977
18	Red C stamp	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	CSPMP reporting	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-502
20	Graduates	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
21	Mortar & Pestle	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
22	Steel spatulas	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
23	Rubber (nonmetallic) spatula	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
25	Weights for Rx balance	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
26	Ointment tile	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

27	Automated storage and distribution system (patient access)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(3); R4-23-654(D)
29	Mechanical storage and counting device	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-615
30	Mechanical counting device	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-616
31	Emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02
32	Automated emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02(E)
33	Automated dispensing system (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.04

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)
2	Dedicated to compounding sterile products	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(1); R4-23-656(5)
3	Isolated from other pharmacy functions	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(2)
4	Restricts entry/access	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(3)

5	Free from unnecessary disturbances airflow	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(4)
6	Nonporous and cleanable floor	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
7	Nonporous and cleanable walls	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
9	Environment ISO 7	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(6)
10	Hood ISO 5	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-110; R4-23-670(E)(F)

NOTES

Limited service mail order pharmacy.
Hours of operation: Weekdays 8:30A-4:30P, Saturday 9:00A-1:00P
No immunizations. No compounding.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 12/28/2023
Receipt Number: 2023170662
Receipt Amount $: 480.00

Pharmacy - Limited Service

PERMIT NO
Y009734

EXPIRES
10/31/2025

Issued to : GoGoMeds West
F&F Scottsdale, LLC.
17250 N HARTFORD DR SUITE 115 SCOTTSDALE, AZ 85255

GoGoMeds West
17250 N HARTFORD DR SUITE 115
SCOTTSDALE, AZ 85255

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : GoGoMeds West
LICENSE NUMBER : Y009734
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

Officer(s)

Name	Title
Ronald Wayde Ferguson	President/Member

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler F&F Scottsdale, LLC dba GoGoMeds West

Pharmacy/Wholesaler License # (if applicable) *Pre CHOW # PH03154

Physical Address 17250 N Hartford Dr, Suite 115

City Scottsdale State AZ Zip 85255

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 602-892-4250 Website www.gogomeds.com

Licensing Company Email ggw.licensing@gogomeds.com

Section 2: Personal Information

First Kristen Middle Walasky Last Meyer

Alias(es, nicknames, name changes, etc.) Maiden name: Walasky

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address 17250 N Hartford Dr, Suite 115

City Scottsdale State AZ Zip 85255

Telephone 602-892-4250 Email k.meyer@gogomeds.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University		08/05-06/08	
Address	City	State	Zip
19555 N 59th Ave	Glendale	AZ	85308
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Valencia Community College		08/01-06/05	
Address	City	State	Zip
1800 S Kirkman Road	Orlando	FL	3281
Diploma/Degree obtained, if any			
AS			

School Name		From - To (MM/YY – MM/YY)	
University at Buffalo		08/99-06/00	
Address	City	State	Zip
12 Capen Hall	Buffalo	NY	14260
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Saranac Lake Central High School		09/95-06/99	
Address	City	State	Zip
79 Canaras Ave	Saranac Lake	NY	12983
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/00-present	[redacted]S Hazelton Dr	Chandler	AZ	85226
03/00-11/00	[redacted]W Ray Rd #1039	Chandler	AZ	85224
07/17-03/00	[redacted]E Rawhide St	Gilbert	AZ	85296
08/10-07/17	[redacted]E Maplewood St	Gilbert	AZ	85297
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
GenRx			08/20 - Present	
Business Address		**City**	**State**	**Zip**
17250 N Hartford Dr, Suite 115		Scottsdale	AZ	85255
Phone	**Title**		**Number of Employed Hours**	
602-892-4250	Pharmacist-in-Charge (PIC)		40/wk	
Description of Duties				
Pharmacist-In-Charge of mail order pharmacy.				

Business Name			From - To (MM/YY – MM/YY)	
One Point Patient Care			05/17 - 08/20	
Business Address		**City**	**State**	**Zip**
3006 S Priest Dr		Tempe	AZ	85282
Phone	**Title**		**Number of Employed Hours**	
480-240-1111	Staff Pharmacist		40/wk	
Description of Duties				
Clinical consultations, formulary review, initial and final review of prescriptions.				

Business Name			From - To (MM/YY – MM/YY)	
Jameson Rx			08/15 - 10/16	
Business Address		**City**	**State**	**Zip**
3800 W Ray Rd, #5		Chandler	AZ	85226
Phone	**Title**		**Number of Employed Hours**	
480-659-3466	Pharmacist-in-Charge (PIC)		40/wk	
Description of Duties				
Oversight of mail order pharmacy operations, scheduling, preparation of compounded prescriptions, initial and final review of prescriptions.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Kristen Meyer, **certify that as the designated representative for**

F&F Scottsdale, LLC dba GoGoMeds West,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kristen Meyer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/25/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kristen Meyer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/25/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Kristen Meyer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04/25/2024

Date

Subscribed and Sworn to before me this 25 day of April.

Notary Public Signature

ALEXANDRA FIERRO
Notary Public - Arizona
Maricopa County
Commission # 659205
My Comm. Expires Nov 28, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site F&F Scottsdale, LLC dba GoGoMeds West

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 17250 N Hartford Dr, Suite 115

City Scottsdale State AZ Zip 85255

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 602-892-4250 Website www.gogomeds.com

Licensing Company Email ggw.licensing@gogomeds.com

Section 2: Personal Information

First Ronald Middle Wayde Last Ferguson

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addre[redacted]Loveland Miamiville Rd

City Loveland State OH Zip 45140

Telephone [redacted] Email r.ferguson@gogomeds.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Cincinnati		1992	
Address	**City**	**State**	**Zip**
3255 Eden Ave	Cincinnati	OH	45229
Diploma/Degree obtained, if any			
Bachelors in Science in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
[redacted]	Loveland Miamiville Rd	Loveland	OH	45140
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
F&F Scottsdale, LLC			2021-current
Business Address	**City**	**State**	**Zip**
17250 N Hartford Dr, Suite 115	Scottsdale	AZ	85255
Phone	**Title**		
602-892-4250	President/Member		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
Specialty Medical Drugstore, LLC. dba GoGoMeds			2013-current
Business Address	**City**	**State**	**Zip**
525 Alexandria Pike, Suite 100	Southgate	KY	41071
Phone	**Title**		
888-795-5826	President		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
F&F Pharmacies, Inc. dba Jungle Jim's Pharmacy			1998 - current
Business Address	**City**	**State**	**Zip**
5484 Dixie Highway	Fairfield	OH	45014
Phone	**Title**		
513-858-3784	President		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
Fortis NC, LLC.			2017-2019, closed.
Business Address	**City**	**State**	**Zip**
N/A, closed.	N/A, closed.	N/A	N/A, closed.
Phone	**Title**		
N/A, closed.	Shareholder		
Description of Duties			
Advisory			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ronald Ferguson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/16/24

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Campbell

I, Ron Ferguson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/16/24

Date

Subscribed and Sworn to before me this 16th day of April.

Heather Johnston

Notary Public Signature

HEATHER JOHNSTON
NOTARY PUBLIC
Kentucky, State At Large
Commission # KYNP45363
My Commission Expires 02/18/2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

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Physical Address 17250 N Hartford Dr. Suite 115

City Scottsdale State AZ Zip 85255

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 602-892-4250 Website www.gogomeds.com

Licensing Company Email ggw.licensing@gogomeds.com

Section 2: Personal Information

First Kip Middle Ryan Last Ferguson

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Ellery Drive

City Cincinnati State OH Zip 45245

Telephone [redacted] Email k.ferguson@gogomeds.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

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Diploma/Degree obtained, if any			
Bachelors in Science in Pharmacy			

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Diploma/Degree obtained, if any			

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Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
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From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
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From - To (MM/YY – MM/YY)	Address	City	State	Zip
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Phone	**Title**			
602-892-4250	Member			
Description of Duties				
Management				

Business Name			From - To (MM/YY – MM/YY)	
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Business Address		**City**	**State**	**Zip**
525 Alexandria Pike, Suite 100		Southgate	KY	41071
Phone	**Title**			
888-795-5826	Member			
Description of Duties				
Management				

Business Name			From - To (MM/YY – MM/YY)	
F&F Pharmacies, Inc. dba Jungle Jim's Pharmacy			1998 - current	
Business Address		**City**	**State**	**Zip**
5484 Dixie Highway		Fairfield	OH	45014
Phone	**Title**			
513-858-3784	Member			
Description of Duties				
Management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kip Ferguson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date 4/17/24

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Campbell

I, Kip R. Ferguson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature **Date** 4/17/24

Subscribed and Sworn to before me this 17th day of April.

Heather Johnston

Notary Public Signature

HEATHER JOHNSTON
NOTARY PUBLIC
Kentucky, State At Large
Commission # KYNP45363
My Commission Expires 02/18/2026

(Seal)

Although the investigation and disciplinary process for each jurisdiction can take months, if not years, the conduct described below occurred over six (6) years ago. Seller, GenRx took robust corrective measures to ensure full compliance and commitment to following all state licensing laws, as well as any federal and state regulation. **Please note these actions are related to the current permit holder GenRx and are included here out of the abundance of caution and in the spirit of full disclosure. There is no conduct to report for the new applicant.**

Oregon – case #2016-0227. On September 21, 2016, Gen Rx received a fully executed Consent Order. Gen Rx agreed to discipline for distributing drugs into Oregon without registering with the Oregon Board of Pharmacy. Gen Rx paid a penalty in the amount of $10,000 with $3,000 stayed pending no further violations.

Alabama – case #16-L-0085. On November 2, 2016, Gen Rx signed a Consent Order. Gen Rx agreed to discipline for operating as a pharmacy in the state of Alabama without being duly permitted by the Board to operate as a pharmacy. Gen Rx paid a penalty in the amount of $4,000.

Alabama (reciprocal) – case #16-L-0168. On February 21, 2017, the Alabama Board adopted GenRx signed a Consent Order, although GenRx was not notified of this acceptance until a later date. An administrative fine by Alabama, for the discipline imposed by Oregon, was $15,000.

Kentucky- case #17-0173. On May 1, 2017, GenRx received confirmation of the acceptance of the Agreed Order. After notification of previous disciplinary action taken by other state boards of pharmacy, the Kentucky Board investigated and found that Gen Rx shipped 14 prescriptions to 7 patients before Gen Rx had a license to conduct business. GenRx paid a $700.00 fine.

California – citation #CI 2016 74685. Gen Rx received a non-disciplinary citation and fine issued by the California Board of Pharmacy in the amount of $1,500.00, which became final upon payment on August 17, 2017. The citation was issued for reciprocal action related to fines issued by Oregon and Kentucky for conduct that occurred in Oregon and Kentucky more than a year prior.

South Carolina – case #2016-70. On February 13, 2018, GenRx received the fully executed Final Order for sending prescriptions to patients in South Carolina without a permit. GenRx paid a penalty of $25,000.00.

Minnesota - On July 16, 2018, GenRx received the fully executed Stipulation and Consent Order for sending prescriptions to patients in Minnesota without a permit. GenRx paid a penalty of $2,500.00.

Maryland - Case #P06911. Representatives from GenRx appeared at a Pre-Charge Case Resolution Conference to discuss dispensing prescription medications into a state without the requisite permit. The committee proposed a $10,000 fine, which was approved by the full Board at their December 19, 2018, meeting. GenRx's confirmation of the full Board approval and receipt of a copy of the fully executed order did not occur until January 2, 2019.

California - Citation #CI 2018 81733. GenRx received a non-disciplinary citation and fine issued by the California Board of Pharmacy in the amount of $1,000. The citation was issued for violations of Business and Professions Code; the non-resident licensee's failure to timely report a change of corporate officers and change of location to the Board. Citations without fines were also rendered for similar conduct in

violation of California Code of Regulations. The action was final December 5, 2018 when GenRx paid the fine.

California - Citation #CI 2017 79007. GenRx received a non-disciplinary citation and fine issued by the California Board of Pharmacy in the amount of $1,500. The citation was issued as reciprocity for conduct in the state of South Carolina and Minnesota. After an appeal, GenRx was notified the citation was final as of March 28, 2019.

Utah - Citation #113128. GenRx received a non-disciplinary citation and fine issued by the Utah Board of Pharmacy in the amount of $300.00 for failure to timely report numerous disciplinary actions from other jurisdictions. The action was final October 17, 2019. GenRx paid the fine but did ask Utah to reconsider. Although GenRx would agree to enter into a consent order with a Board of Pharmacy, GenRx often had to wait for the full Board committee to approve and fully execute the order at a future board meeting. Oftentimes, GenRx would not receive confirmation until days or weeks after the full Board committee approved, making disclosure within 10 days an impossibility. As such, GenRx typically disclosed discipline within 10 days of its confirmation the full Board adopted the agreed up on Consent Order and its receipt of the fully executed order. Despite its dispute of the action by Utah, GenRx disclosed the action to every state in which it holds a non-resident license in the event a Board would require such disclosure.

On November 12, 2019, Utah reduced the fine and renumbered the citation from #113128 to #100556. On January 31, 2020 the Utah Division of Occupational and Professional Licensing set aside the citation order and dismissed the citation without prejudice.

Alabama (reciprocal) - Case #17-L-0057. The Alabama State Board of Pharmacy Issued a Statement of Charges and Notice of Hearing to GenRx for Alabama pharmacy violations as reciprocal discipline for the discipline imposed by other Boards of Pharmacy. GenRx agreed to a $10,000 fine. The action became final on December 17, 2019, when it was fully executed by the Alabama State Board of Pharmacy.

Vermont – Docket No. 2020-82. On December 2, 2020, the Vermont Board of Pharmacy accepted a Stipulation and Consent Order related to GenRx Pharmacy dispensing medications to Vermont residents prior to being fully licensed and accredited by the Vermont Board of Pharmacy. The stipulation and Consent Order imposed a $7,500 fine. A copy of the fully executed order was received by GenRx on December 4, 2020.

Alabama (reciprocal) – Case No: 21-L-0004. The Alabama State Board of Pharmacy Issued a Statement of Charges and Notice of Hearing to GenRx for Alabama pharmacy violations as reciprocal discipline for the discipline imposed by the Vermont State Board of Pharmacy. GenRx agreed to a $20,000 fine. The action became final on June 15, 2021, when it was fully executed by the Alabama State Board of Pharmacy.

RECEIVED
SEP 07 2016
OREGON BOARD OF PHARMACY

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of	)	Case No. 2016-0227
	)	
GENRX	)	CONSENT ORDER
	)	
Respondent	)	
	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Civil Penalty; Answer Required ("Notice") regarding the Respondent in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the Respondent as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the Respondent is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the Respondent admits that the facts alleged in the above-noted Notice are true, that the Respondents conduct, as admitted, violated the statutes and rule cited in the Notice, and that legal cause exists pursuant to ORS 689.335, 689.405, and 689.445 for disciplinary action by the Board; and

WHEREAS, the Respondent consents to the disciplinary action as set forth herein;

The Board finds that the allegations in the Notice are true and hereby:

1. The Respondent shall pay a civil penalty to the Board in the amount of $10,000 with $3,000 stayed pending no further violations of ORS 689.305 for three years. If respondent violates any term or condition of this Consent Order, within three years of the effective date of this Consent Order, the Board may take action to, lift the stayed portion of the civil penalty. Payment of the $7,000 portion of the civil penalty not stayed to be made within ten days from the date this Consent Order becomes final.

2. This Consent Order shall become effective immediately upon issuance by the Board.

3. In the event that the Respondent fails to timely pay the civil penalty as ordered herein, the Board may take further action, after notice and hearing.

CONSENT

I hereby acknowledge that I am the authorized representative of registrant. On behalf of the registrant, I hereby acknowledge that I have read and understand the above-noted Notice and the terms of the Consent Order. I hereby acknowledge that I understand that the Consent Order with incorporated Notice is a public record and shall be available via the Board's online licensure verification; is available upon written request pursuant to public disclosure laws; and shall be reported to the National Practitioner Data Bank as required by federal law. I agree to the Board entering the Consent Order.

Authorized Representative
GENRX
Respondent

Date 8/31/16

IT IS SO ORDERED.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Gary Miner, R.Ph.,
Compliance Director

Date 9/9/16

IN THE MATTER OF: **GENRX PHARMACY** **Non-Resident Pharmacy** **Permit Number: 114306**	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY** **CASE NO: 16-L-0085**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against GenRX which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as Exhibit "A."

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and GenRX through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that GenRX violated the provisions of law based upon the conduct set out in Count One of the Statement. All other Counts shall be dismissed with prejudice

2. GenRX shall pay an administrative fine in the amount of Four Thousand Dollars ($4,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. GenRX expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform

Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. GenRX further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, GenRX hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. GenRX acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against GenRX's permit, including, but not limited to revocation.

6. GenRX acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. GenRX acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 2nd of November 2016.

GENRX

BY: (MARK BOSSEN)

ITS: Chairman & CEO

Spencer H. Larche, attorney for GenRX

ALABAMA STATE BOARD OF PHARMACY

By:
Timothy A. Martin, Pharm.D., President

By:
James W. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

IN THE MATTER OF:	)	
GENRX PHARMACY	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
Non-Resident Pharmacy Permit Number: 114306	)	**CASE NO: 16-L-0168**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against GenRX Pharmacy which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A"** as well as discipline imposed by the Oregon State Board of Pharmacy (Oregon Discipline).

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and GenRX Pharmacy through its counsel engaged in negotiations and as a result the matters at issue, to include the Oregon Discipline were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that GenRX Pharmacy violated the provisions of law based upon the conduct set out in all Counts of the Statement, and based upon the Oregon Discipline.

2. GenRX Pharmacy shall pay an administrative fine in the amount of Fifteen Thousand Dollars ($15,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. GenRX Pharmacy expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. GenRX Pharmacy further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, GenRX Pharmacy hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. GenRX Pharmacy acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against GenRX Pharmacy's permit, including, but not limited to revocation.

6. GenRX Pharmacy acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. GenRX Pharmacy acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on

the advice of its attorney.

DONE this the 8th of February ,2017.

GENRX PHARMACY

BY:

ITS: CEO

Spencer Larche, attorney for GenRX Pharmacy

DONE this the 21 of February ,2017.

ALABAMA STATE BOARD OF PHARMACY

By:
Buddy Bunch, Pharm., President

By:
James T. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

FO - 100/2156

RECD KYBOP 04/20/17

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 17-0173

IN RE: GenRx Pharmacy
17250 N Hartford DR STE 115
Scottsdale AZ 85255
Permit # AZ1913

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("the Board") and GenRx Pharmacy ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacies.

(2) Respondent is licensed as an out-of-state pharmacy pursuant to KRS 315.0351, but was not licensed by the Board until March 10, 2015.

(3) (a) On various dates in 2016, the Board was notified of disciplinary action taken against Respondent by other state boards of pharmacy.

(b) The Board's investigation revealed that Respondent shipped 14 prescriptions to 7 patients in Kentucky between October 24, 2014 and March 10, 2015, before Respondent had a license to conduct business in Kentucky.

(c) The above actions constitute a violation of KRS 315.0351(1) and subject the Respondent to discipline pursuant to KRS 315.121(1)(b).

(4) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) The Respondent is fined $700.00 payable on or before April 14, 2017. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes St., Frankfort, Kentucky, 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that it was fully and completely informed of its right to due process, that it fully understands these rights, and that it knowingly, voluntarily, and willingly agrees to waive these rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Scott Greenwell, President
Kentucky Board of Pharmacy

13 April 2017
Date

Gen Rx Pharmacy
Respondent

4/12/17
Date

3078

GenRx

August 24, 2017

VIA CERTIFIED MAIL
California Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

RE: **Notification of Non-Disciplinary Citation Imposed by the State of California**
License Number: NRP 1462
Payment made by GenRx on August 18, 2017

To Whom It May Concern:

This is to notify you that GenRx has received a ***nonsisciplinary citation*** and fine issued by California State Board of Pharmacy. The citation was issued as ***reciprocal action*** related to fines issued by Oregon and Kentukcy for conduct that occurred in Oregon and Kentucky more than a year ago. Please note, your office received notifications and corrective action reports for the Kentucky and Oregon matters in a previous correspondence. A copy of the California notice is attached herein as Exhibit A.

This is a courtesy copy in case your state requires a report of actions taken by other state boards of pharmacy. If no such report is required, please disregard.

Yours Truly,

Mark Boesen, Pharm.D., J.D.
CEO & Chairman

17250 NORTHHARTFORD DRIVE • SUITE 115 • SCOTTSDALE, AZ 85255
DIRECT TELEPHONE (602) 616-8831 • FAX (602) 357-4911

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

July 19, 2017

GENRX PHARMACY, A GENRX COMPANY
ATTN: SAMUEL ELLIOTT WEBSTER, PIC
17250 N HARTFORD DR STE 115
SCOTTSDALE, AZ 85255

RE: CI 2016 74685
GENRX PHARMACY, A GENRX COMPANY
NRP 1928

The attached Citation CI 2016 74685, has been issued to GENRX PHARMACY, A GENRX COMPANY, NRP 1928. A copy has been sent to the non-resident pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to ensure the non-resident pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the non-resident pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Ericka Busby, Enforcement Analyst at (916) 574-7731.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2016 74685	GENRX PHARMACY, A GENRX COMPANY, NRP 1928

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775;

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4301 subd. (n)	Unprofessional Conduct - Out of state disciplinary action	$1,000.00
Bus. & Prof. Code § 4301 subd. (n)	Unprofessional Conduct - Out of state disciplinary action	$500.00

CONDUCT:

Business and Professions Code section 4301(n) authorizes the Board to take action against a licensee for the revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required. Specifically, on Sep. 9, 2016, the Oregon Board of Pharmacy ordered GenRx Pharmacy to pay $7,000 ($10,000, stayed $3,000) after it found that GenRx Pharmacy distributed drugs into Oregon from May 16, 2014, to May 7, 2016, without registering as a drug outlet.

Business and Professions Code section 4301(n) authorizes the Board to take action against a licensee for the revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required. Specifically, on April 13, 2017, the Kentucky Board of Pharmacy (KYBP) ordered GenRx Pharmacy to pay $700, after it found that GenRx Pharmacy shipped 14 prescriptions to seven patients in Kentucky from Oct. 24, 2014 to March 10, 2015, prior to receiving its Kentucky license, and after KYBP received notifications on various dates in 2016 of disciplinary actions by other states.

CITATION ISSUED ON: July 19, 2017 | **TOTAL AMOUNT OF FINE(S): $1,500.00**

PAYMENT OF FINE(S) DUE BY: August 18, 2017

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING, AND REGULATION
BEFORE THE STATE BOARD OF PHARMACY

RECEIVED
FEB 13 2018
By

In the Matter of:

GenRx Pharmacy,
License No. PY.16212,

Mark Boesen,
Permit Holder

Case No. 2016-70

Respondent.

FINAL ORDER

This matter came before the State Board of Pharmacy (the "Board") on November 17, 2017, with a quorum present, for a hearing on the Memorandum of Agreement and Stipulations ("MOA") in the above-referenced matter. In the MOA, Respondent elected to dispose of the matter pursuant to S.C. Code Ann. § 1-23-320(f) (2005, as amended), in lieu of, *inter alia*, a full hearing before the Board.

Patrick Hanks, Esquire, Chief Disciplinary Counsel, represented the State. The Respondent was represented by Travis Dayhuff, Esquire. GenRx Pharmacy appeared through its permit holder, Mark Boesen. GenRx Pharmacy's in-house compliance administrator and its general counsel also attended the hearing. Board members Leo Richardson, Marvin Hyatt and Robert Hubbard did not participate in this matter. The remaining Board members voted for the sanctions set forth below.

FINDINGS OF FACT

Respondent and the State stipulated to the following findings of fact, which the Board adopts:

1. Respondent is a full service retail and mail order pharmacy located at 17250 North Hartford Drive, Suite 115, Scottsdale, AZ 85255. Respondent does not dispense compounded medications or controlled substances.

2. Respondent submitted an application for a nonresident pharmacy permit to the Board's staff, which application was attached to the MOA for the Board's consideration.[1]

3. In response to the nonresident pharmacy permit application question "[d]ate your pharmacy began dispensing to South Carolina," Respondent's Pharmacist-in-Charge ("PIC") answered, "not yet." Respondent's PIC signed this application on February 26, 2015.

4. On June 22, 2015, Respondent mailed the application for a nonresident pharmacy

[1] Exhibits referenced herein were identified and admitted into evidence for the Board's consideration during the final order hearing, but are not attached hereto.

permit to the Board's staff. This application was stamped received on June 30, 2015.

5. On October 15, 2015, Respondent's PIC appeared before the Board's Nonresident Application Review Committee for a hearing. At this hearing, Respondent's PIC was not asked whether Respondent had commenced shipping product in the South Carolina. A copy of the transcript of that Nonresident's Applicant Review Committee hearing was attached to the MOA for the Board's consideration.

6. On October 22, 2015, Respondent was issued a nonresident pharmacy permit, and on July 1, 2017, this permit was renewed. Copies of the permits were attached to the MOA for the Board's consideration.

7. On or about May 3, 2016, after receiving a complaint that Respondent had shipped product into South Carolina prior to receiving a permit, the Board's staff asked Respondent to conduct an internal investigation to determine how many prescriptions Respondent had shipped to patients in South Carolina from May 1, 2015, until October 21, 2015.

8. Respondent's PIC reported to the Board's staff that Respondent had shipped 695 prescriptions to South Carolina patients between May 1, 2015 and October 21, 2015.

9. In response, Respondent took corrective action that included modification of the pharmacy's software to block the processing of orders for patients in states where Respondent is not licensed, and hiring a new administrator who is both a pharmacist and an attorney, and who has experience implementing robust pharmacy compliance programs, to oversee compliance. Respondent also terminated the employment of the PIC who completed the application and appeared before the Nonresident Application Review Committee in October 2015.

10. On or about October 25, 2016, the South Carolina Department of Labor, Licensing, and Regulation ("LLR") proposed a Consent Agreement to Respondent to resolve this matter that included a public reprimand and a $500 fine. Respondent agreed to the terms of this Consent Agreement and returned an executed copy of the Consent Agreement with a check for $500 to LLR. A copy of that Consent Agreement was attached to the MOA for the Board's consideration. The Board takes judicial notice that the Board never accepted that Consent Agreement and it was never signed by the Board's chair or signed by counsel for LLR.

11. On or about March 16, 2017, LLR proposed a second Consent Agreement to Respondent to resolve this matter that included a public reprimand and $5,000 fine. Respondent agreed to the terms of the second Consent Agreement and returned the executed copy of the Consent Agreement with a check for $4,500 to LLR. A copy of that Consent Agreement was attached to the MOA for the Board's consideration. The Board takes judicial notice that the Board never accepted the second Consent Agreement and it was never signed by the Board's chair or signed by counsel for LLR.

12. LLR cashed Respondent's check that accompanied the first and second Consent Orders and currently holds these funds.

13. On June 14, 2017, the second Consent Agreement was presented by LLR to the Board for approval. The Board rejected the second Consent Agreement primarily because of concerns that Respondent may have intentionally misled the Board about shipping into South

Carolina without a permit. A copy of the transcript of the Board's consideration of that matter at its June 14, 2017 meeting was attached to the MOA for the Board's consideration.

CONCLUSIONS OF LAW

1. The Board has jurisdiction in this matter.

2. Respondent acknowledged in the MOA that Respondent's conduct as stipulated in the MOA constitutes a violation of S.C. Code Ann. §§40-43-89(N)(1) and 40-43-140(A)(1)(a), which admission the Board accepts.

3. Upon finding that a permittee's conduct is grounds for discipline under any of the provisions of the Pharmacy Practice Act (S.C. Code Ann. § 40-43-10, *et seq.*), the Board has the authority to, suspend, revoke, deny, or refuse to renew the permit or impose a fine or other disciplinary action, including a public reprimand. S.C. Code Ann. §§ 40-43-140 and 150 (2011). South Carolina Code Ann. Regs. 99-46 (Supp. 2017) authorizes the Board to impose a fine of $500 per violation, not to exceed $25,000 per action. Further, S.C. Code Ann. § 40-43-140(A)(2) provides that a person who distributes or delivers drugs or devices to a person not permitted in accordance with this chapter is subject to a fine to be imposed by the board not to exceed one thousand dollars for each offense in addition to such other disciplinary action the board may take under this chapter. Here, Respondent admitted to sending 695 prescriptions to patients in South Carolina over an approximately six-month period without a permit. The Board concludes that Respondent's actions warrant imposition of the maximum fine of Twenty-Five-Thousand and 00/100 Dollars ($25,000.00) and a public reprimand.

4. The sanctions and conditions imposed by this Order are within the scope of those permitted by law and are designed not to punish the Respondent, but to protect the life, health and welfare of the people at large.

IT IS THEREFORE ORDERED:

1. Respondent is publicly reprimanded.

2. Respondent is assessed a civil penalty of Twenty-Five Thousand and 00/100 Dollars ($25,000.00), which must be paid within Sixty (60) days of the date of this Order.

AND IT IS SO ORDERED.

STATE BOARD OF PHARMACY

Terry A. Blackmon

Terry A. Blackmon, R.Ph.
Board Chair

February 10, 2018

South Carolina Department of Labor, Licensing and Regulation

STATE OF SOUTH CAROLINA

COUNTY OF LEXINGTON

In the Matter of:

GenRx Pharmacy

PY . 16212

CERTIFICATE OF SERVICE BY MAIL

This is to certify that the undersigned has this date, February 13, 2018, served the Final Order in the above entitled action upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, or in the Interagency Mail Service addressed to the party(ies) or their attorney(s) to the following address:

GENRX PHARMACY
17250 N. HARTFORD DRIVE, SUITE 115
SCOTTSDALE AZ 85255

TRAVIS DAYHUFF, ESQUIRE
P. O. BOX 11070
COLUMBIA, SC 29211

Timothy B. Havens

Tim Havens
Administrative Coordinator
SC Department of Labor, Licensing
and Regulation

MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

2829 University Ave. SE., #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (612) 617-2262
MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:
Metro and Non-Metro; 800-627-3529
E-Mail Address: Pharmacy.Board@state.mn.us
Web Site: www.pharmacy.mn.gov

PERSONAL & CONFIDENTIAL

July 12, 2018

GenRx Pharmacy
Attn: Mark Boesen, CEO
17250 N Hartford Drive, Suite 115
Scottsdale, AZ 85255

RECEIVED JUL 16 2018

Re: In the Matter of GenRx Pharmacy
Pharmacy License No. 265062

Dear Mr. Boesen,

Enclosed and served upon you in the above-referenced matter is the Stipulation and Consent Order adopted by the Minnesota Board of Pharmacy.

Sincerely,

Cody Wiberg

Cody Wiberg, Pharm.D., M.S., R.Ph.
Executive Director

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
GenRx Pharmacy
License Number: 265052

STIPULATION AND CONSENT ORDER

STIPULATION

GenRx Pharmacy ("Licensee"), and the Minnesota Board of Pharmacy Complaint Review Panel ("Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and pharmacists and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

NOTICE AND WAIVERS

3. After a review of the facts, Licensee and the Review Panel, composed of Board members Rabih Nahas and James Bialke, agree that this matter may be resolved by mail with a Stipulation and Consent Order.

4. Licensee was advised by the Board's representative that it may choose to be represented by legal counsel. Licensee has waived legal representation. Nicholas Lienesch, Assistant Attorney General, represented the Panel in this matter.

III.

FACTS

5. On May 17, 2016, the Board licensed Licensee as a non-resident pharmacy in Minnesota.

6. By letter dated September 22, 2016, Licensee notified the Board that on or about September 9, 2016, the Oregon Board of Pharmacy took disciplinary action against Licensee ("Oregon Order") for distributing drugs into Oregon without registering as a drug outlet.

5. On or about October 18, 2016, a Board Surveyor called Licensee's Chairman and Chief Executive Officer ("CEO"), to ask whether Licensee dispensed prescriptions to Minnesota patients prior to the active date of Licensee's license. Licensee's CEO indicated prescriptions had been dispensed to Minnesota patients before the license was active and stated he would submit a list of those prescriptions dispensed.

6. On November 3, 2016, the Board Surveyor received an email from Licensee's CEO, indicating that there may have been as many as ninety-five prescriptions dispensed to Minnesota patients prior to the active date of Licensee's license, and that it was a mistake and should have never occurred. The CEO stated that a number of policies and computer fail-safe settings had been implemented to prevent this activity for states in which the pharmacy is not licensed.

7. By letter dated March 10, 2017, Licensee notified the Board that on or about February 21, 2017, the Alabama Board of Pharmacy took disciplinary action against Licensee ("Alabama Order") due to the disciplinary action taken in Oregon.

8. On or about April 13, 2017, the Board Surveyor sent a letter to Licensee requesting additional information about prescriptions dispensed to Minnesota patients prior to the active date of Licensee's license.

9. By letter dated May 4, 2017, Licensee notified the Board that on or about April 13, 2017, the Kentucky Board of Pharmacy took disciplinary action against Licensee ("Kentucky Order") for shipping prescription drugs into Kentucky without a license and disciplinary actions in other states.

10. On or about May 15, 2107, the Board received a response from Licensee including a list of prescription shipped to Minnesota patients prior to Licensee's license becoming active. Between January 19, 2015 and May 12, 2016, Licensee dispensed and shipped one hundred and twenty-one prescriptions to Minnesota patients.

11. By letter dated August 24, 2017, Licensee notified the Board that on July 19, 2017, the California Board of Pharmacy fined Licensee ("California Order") due to disciplinary actions taken in Oregon and Kentucky.

12. By letter dated February 22, 2018, Licensee notified the Board that on February 13, 2018, the South Carolina Board of Pharmacy took disciplinary action against Licensee ("South Carolina Order") for shipping prescriptions into South Carolina without a permit.

IV.

LAWS

13. Licensee acknowledges the conduct described in sections III., above constitutes a violation of Minn. Stat. § 151.071, subd. 2(6), (7) and (12); Minn. Stat. § 151.19, subd. 1; Minn. R. 6800.0300; and Minn. R. 6800.2250, subp. 1.K. Licensee further acknowledges that this conduct justifies the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

A. Reprimand

14. The Board **REPRIMANDS** Licensee for the conduct outlined in sections III., above.

B. Civil Penalty

15. The Board imposes a **CIVIL PENALTY** in the amount of $2,500.00. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

16. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future

practice, an additional period of suspension, additional conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

17. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under Minnesota state and U.S. federal constitutions, statutes, or rules.

18. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

19. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

20. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

21. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may

approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

22. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

23. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

24. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4. Board Member

25. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

BOARD OF PHARMACY COMMITTEE
ON PROFESSIONAL STANDARDS

GENRX PHARMACY
Licensee

Dated: 6/4/18

RABIH NAHAS
Board Member

Dated: 7/11/18

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** on Licensee's license, and adopts all of the terms described above on this 11TH day of July, 2018.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

IN THE MATTER OF	*	**BEFORE THE**
GENRX PHARMACY	*	**MARYLAND BOARD**
Permit No. P06911	*	**OF PHARMACY**
	*	**Case No. 18-214**

* * * * * * * * * * * * * *

PRE-CHARGE CONSENT ORDER

Background

Between August 2016 and July 2018, the Maryland Board of Pharmacy (the "Board") received self-reports of disciplinary actions taken in six other states against GenRx Pharmacy (the "Pharmacy"), Permit No. P06911. Because most of the other disciplinary actions concerned practicing pharmacy in those states without an active pharmacy permit, the Board subpoenaed the Pharmacy's records of prescription drugs dispensed into Maryland between January 1, 2010, and August 21, 2015. The information provided by the Pharmacy indicated that the Pharmacy dispensed 7,354 prescriptions into Maryland before it received a permit from the Board on August 22, 2015.

In lieu of instituting formal proceedings against the Pharmacy, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 et seq., the Board held a Pre-Charge Case Resolution Conference ("CRC") with the Pharmacy on August 22, 2018. As a result, the Board and the Pharmacy have agreed to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

1. The Pharmacy began operating as a pharmacy in Maryland under Permit No. P06911 on August 22, 2015. The Pharmacy's permit is currently active and is set to expire on May 31, 2020.

2. Between August 2016 and July 2018, the Pharmacy self-reported to the Board disciplinary actions taken by Boards of Pharmacy in Oregon, Kentucky, South Carolina, and Minnesota, all for shipping prescription drugs to patients in those states without a permit. The Pharmacy also disclosed reciprocal disciplinary actions taken by Boards of Pharmacy in Alabama and California based on the other disciplinary actions reported to the Board.
3. On April 25, 2018, the Board issued a *subpoena duces tecum* to the Pharmacy, requesting dispensing records for all prescriptions dispensed by the Pharmacy into Maryland between January 1, 2010, and August 21, 2015. The responsive documents submitted by the Pharmacy indicated that it dispensed 7,354 prescriptions into Maryland without an active pharmacy permit between July 28, 2014, and August 21, 2015.
4. At the CRC, the Pharmacy admitted to dispensing prescription drugs into Maryland without an active permit, although it noted that it did not dispense any compounded drugs or controlled dangerous substances into Maryland. The Pharmacy stated that after it learned of its licensing deficiencies in several states, it discharged some senior staff and brought in a new chief executive officer to clean up any quality assurance issues. The Pharmacy noted that the root causes of its licensure issues were a knowledge deficit and certain system deficiencies.
5. The Pharmacy also stated that it took several steps to ensure that no further licensing deficiencies occur. Specifically, the Pharmacy stated that it implemented a shipping software system that does not allow it to print labels for shipping into states where it does not have a permit, hired general counsel to survey its compliance with various state laws, and created an anonymous ethics hotline. The Pharmacy also received URAC mail order accreditation on August 1, 2018.

CONCLUSION OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Pharmacy is subject to disciplinary action in accordance with Md. Code Ann., Health Occ. §§12-401(a), 12-703, and 12-707(e), and COMAR 10.34.11.09D(1)(b).

ORDER

Based on an affirmative vote of a majority of the Board, it is this 19th day of December, 2018, hereby:

ORDERED that the Pharmacy shall pay a fine in the amount of $10,000.00, payable to the Maryland Board of Pharmacy, within thirty (30) days of the date of this Order; and be it further,

ORDERED that failure to pay in full the above fine within thirty (30) days of the date of this Order shall be considered a violation of this Order, and after notice and opportunity for a show cause hearing may subject the Pharmacy to further discipline such as suspension, revocation or further fines based on the violations cited in this Order; and be it further,

ORDERED that the Pharmacy shall practice in Maryland at all times in accordance with the Maryland Pharmacy Act; and be it further

ORDERED that this is a formal order of the Maryland Board of Pharmacy and as such is a public document pursuant to the Md. Code Ann., Gen. Provisions § 4-333(b).

12/19/18
Date

Kevin Morgan, Pharm. D.
President, Maryland Board of Pharmacy

CONSENT

1. By signing this Consent, the Pharmacy submits to the foregoing Consent Order as a resolution of this matter in lieu of formal charges, which process would have afforded the Pharmacy the right to a full evidentiary hearing. The Pharmacy consents and submits to the foregoing Findings of Fact, Conclusions of Law, and Order as if made after a full evidentiary hearing in which the Pharmacy would have the right to counsel, to confront witnesses, to give testimony, to call witnesses on its behalf, and to all other substantive and procedural protections provided by law.
2. By signing this Consent, the Pharmacy waives any rights it may have had to contest the findings and determinations contained in this Consent Order.
3. The Pharmacy acknowledges that this is a formal order of the Board and as such is a public document.
4. The Pharmacy acknowledges the legal authority and the jurisdiction of the Board to enter into and enforce this Consent Order.
5. The Pharmacy signs this Consent Order freely and voluntarily and after having had the opportunity to consult with counsel. The Pharmacy fully understands the language, meaning, and effect of this Consent Order.

GenRx Pharmacy
Permit No. P06911

12/7/2018
Date

Jay Aldrich, President and Secretary
GenRx Pharmacy

STATE OF Arizona
COUNTY/CITY OF Maricopa :

I hereby certify that on this 7th day of December, 2018, before me, a Notary Public of the State of Arizona and County/city aforesaid, personally appeared Jay Aldrich, on behalf of GENRX PHARMACY, and made an oath in due form that the foregoing Consent was his voluntary act and deed.

Allyson L. Snow
Notary Public
My commission expires: 6.7.22

ALLYSON L. SNOW
Notary Public, State of Arizona
Maricopa County
Commission # 550444
My Commission Expires
June 07, 2022

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing

GARY R. HERBERT
Governor
SPENCER J. COX
Lieutenant Governor

FRANCINE A. GIANI
Executive Director

MARK B. STEINAGEL
Division Director

September 27, 2019

GenRx Pharmacy
17250 N Hartford Dr Ste 115
Scottsdale, AZ 85255

To Whom It May Concern:

The Division has received information concerning disciplinary action imposed upon your pharmacy by another jurisdiction which you provided with your license renewal application. Pursuant to U.C.A. 58-17b-614, *you are required to report this information within 10 days of the final order.*

> 58-17b-614. Notification.
> (1) A pharmacy shall report in writing to the division not later than 10 business days before the date of:
> (e) any matter or occurrence that the board requires by rule to be reported;
> (f) a final administrative disciplinary order against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is a class D pharmacy;

Based upon your non-compliance with the Division's notification requirements, and pursuant to U.C.A 58-17b-401; the Division is imposing a citation, which you will find enclosed with this letter.

Additionally, you will find a "Notice of Response" enclosed that must be completed and returned *within 20 calendar days.*

If you have any questions, please contact our office at (801) 530-6630.

Thank you,

Alicia Moran
Pharmacy Inspector

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing
ATTN: Citation Coordinator
160 East 300 South
P.O. Box 146741
Salt Lake City, Utah 84114-6741

Telephone: (801) 530-6628
Fax: (801) 530-6511
Website: www.dopl.utah.gov

100556

CITATION

ISSUED TO: GenRx Pharmacy			
PROFESSION: Class D Pharmacy	LICENSE #: 9452529-1708		CASE #: 113128
DOB: / /	DL #:		SSN/EIN #: 46-4322447
BUSINESS ADDRESS: 17250 N Hartford Dr	CITY: Scottsdale	STATE: AZ	ZIP: 85255
BUSINESS PHONE: 866-453-6143	BUSINESS EMAIL: contracts@genrx2u.com		
HOME ADDRESS:	CITY:	STATE:	ZIP:
HOME PHONE:	HOME EMAIL:		

LOCATION OF OFFENSE: GenRx Pharmacy 17250 N Hartford Dr Ste 115 Scottsdale AZ 85255

DATE OF OFFENSE: 09 / 12 / 2019 DATE ISSUED: 09 / 27 / 2019

OFFENSE CODE	DESCRIPTION
58-1-501-2(a)	violating, or aiding or abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title;
58-17b-502(1)(l)	Failing to report to the Division any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court for conduct that in substance would be considered unprofessional conduct under this section;

REMARKS: On 09/12/2019, the Division received an application for licensure renewal from GenRx Pharmacy, a Class D out of state mail order pharmacy located in Scottsdale, Arizona. Upon reviewing the renewal application, it was found the pharmacy had disciplinary action taken against their license from the AL Board of Pharmacy on 02/08/17 & 05/13/19, KY Board of Pharmacy on 04/13/17, CA Board of Pharmacy on 07/19/17 & 12/26/18, MN Board of Pharmacy on 07/11/18 and the MD Board of Pharmacy on 12/7/18. The Respondent failed to report the disciplinary action to the Division within 10 days of the action. Pursuant to U.C.A. 58-17b-614, a pharmacy shall report in writing to the Division not later than 10 business days any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency or court.

*** FINE PURSUANT TO R156-17b-402 (25) ***

PERSON SERVED: Mailed To GenRx Pharmacy

SERVED BY: Alicia Moran

☑ FINE $ 300.00

☑ CEASE AND DESIST ORDER

I ACKNOWLEDGE RECEIPT OF THIS CITATION AND CERTIFY THAT I HAVE READ AND UNDERSTAND THE RIGHTS ADVISEMENT CONTAINED BELOW AND HAVE BEEN PROVIDED A NOTICE OF RESPONSE.

RECIPIENT'S SIGNATURE

10/16/19
DATE

I CERTIFY THAT THE INFORMATION IN THIS CITATION IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

INVESTIGATOR'S SIGNATURE

READ CAREFULLY

1. **If you wish to contest this citation at a hearing, you must notify the Division in writing within 20 calendar days of receipt. The hearing will be conducted according to Title 63 G, Chapter 4.**
2. **If you do not contest the citation within 20 calendar days of receipt, the citation will become a final order of the Division and is not subject to further agency review.**
3. **Failure to comply with a final order of the Division is a Class A misdemeanor. The Division may refuse to issue or renew or may suspend, revoke, or place on probation a license you hold or apply for.**

DIVISION COPY

DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING
Heber M. Wells Building
160 East 300 South
PO Box 146741
Salt Lake City, UT 84114-6741
Telephone: (801) 530-6628
FAX: (801) 530-6511

NOTICE OF RESPONSE

Citation #: 100556	Date of Citation: 9/27/19	
Name: AenRx Pharmacy	Phone: (602) 892.4250	
Address: 17250 N. Hartford Dr Suite 115		
City: Scottsdale	State: AZ	Zip: 85255

You must respond within 20 calendar days to your citation as outlined below.

If you fail to timely respond, the citation will become the final order of the Division and may result in denial of future licensure or disciplinary action against a license you currently hold.

Select only one of the following:

☐	1. I admit committing the offense, choose not to contest the citation, and hereby submit the fine imposed (if applicable).
☑	2. I admit committing the offense, hereby submit the fine imposed (if applicable) with a written explanation of the circumstances of the offense and request that the fine be reduced or the sanction be modified.
☐	3. I admit committing the offense, but I request a pre-citation hearing conference to explain the circumstances of the offense. *(On the back of this form please submit a brief written explanation of the circumstances of the offense.)*
☐	4. I deny committing the offense and request a hearing to contest the citation. *(On the back of this form please provide a written response to the alleged citation.)*

I certify that I have knowingly and voluntarily made the above election of rights. I understand that if I request a hearing the Division will notify me in writing of the hearing date and that if I fail to appear at the hearing a default judgment will be entered against me.

Signature: [signature]	Date of Signature: 10/16/19

Revised 01/22/2018

17250 N. Hartford Dr.
Ste. 115
Scottsdale, AZ 85255
Direct Line: 602-892-4250

October 16, 2019

VIA FEDERAL EXPRESS
State of Utah
Department of Commerce
Division of Occupational and Professional Licensing
ATTN: Citation Coordinator
160 East 300 South
Salt Lake City, UT 84114-6741

RE: GenRx Pharmacy, Utah License #9452529-1708

Dear Sir or Madam:

We are in receipt of your letter dated September 27, 2019 (copy enclosed) with an associated "Citation and Fine" for $300.00 for failure to report numerous disciplinary actions with 10 days of the action[1] pursuant to U.C.A. 58-17b-614.

Enclosed please find a check payable to "DOPL" (Division of Occupational and Professional Licensing) in the amount of $300.00 to satisfy the "Citation and Fine". I have also enclosed the "Notice of Response" as instructed and elected Option #2; "I admit committing the offense, hereby submit the fine imposed (if applicable) with a written explanation of the circumstances of the offense and **request that the fine be reduced or the sanction be modified.**"

I have taken the opportunity to review discipline records. I believe I understand where the confusion lies. As you know, agreement as to the terms of a Consent Order with Board staff is not always a guarantee the full Board committee will adopt the Order. GenRx has adopted a policy of notifying jurisdictions of discipline within 10 days of our *confirmation* that the Order has been adopted. This is for good reason. In the case of our South Carolina discipline (not referenced in your letter, but timely disclosed nevertheless), GenRx learned that premature disclosure of a proposed first Order GenRx *expected* South Carolina to adopt resulted in the necessity to rescind the disclosure. In fact, South Carolina proposed two Consent Orders that GenRx accepted that were subsequently rejected by the full South Carolina Board. GenRx ultimately appeared in front of the full board the third time, which resulted in an Order that was eventually adopted. As you can imagine, this created confusion for numerous jurisdictions asking

[1] The Citation references an Alabama action on 5/13/19. Please note there is no final action from Alabama at this time in reference to this reciprocal discipline. GenRx disclosed this as an investigation on its Utah renewal application.

for a fully executed Order after our premature disclosure because the first Order was never countersigned and could not be provided.

Thus, GenRx's policy has been to disclose discipline after *confirmation* the Consent Order is adopted and countersigned. Many times this confirmation does not come until weeks after the Board adopts and countersigns the order, making disclosure within 10 days an impossibility. As an example, although GenRx might have signed the Maryland Consent Order on December 7, 2018, the full Maryland Board did not meet, adopt and fully execute the Order until December 19, 2018. Undersigned counsel had to follow-up with the Maryland Board and did not receive a copy of the Order until January 2, 2019. GenRx mailed its notifications to each state in which it held a non-resident license (including Utah) on January 4, 2019. Even had GenRx been able to confirm the Maryland Board had adopted the Order on December 19, 2018, disclosure without a fully executed copy would be impractical as the final Order would be expected to be attached as an exhibit to the disclosure letter.

GenRx acknowledges that perhaps it could have been more specific in its disclosures regarding when complaints were issued, when GenRx accepted an order, when the order was made final, and most importantly, when GenRx received notification with a copy of the fully executed Order. However, GenRx would respectfully request that DOPL consider that, even in the event an organization discloses late, they are still disclosing. It would seem to be poor public policy to penalize an organization for disclosing discipline a few days late and would actually incentivize people with ill intent to not disclose at all and risk their lack of disclosure not be discovered.

In the event Utah's Division of Occupational and Professional Licensing choose to reduce of modify the sanction as requested, GenRx will still be required to disclose this Citation and Fine to each jurisdiction in which it holds a non-resident license within 10 days, or risk similar actions in other states. Nevertheless, GenRx wishes to explain the underlying circumstances in hopes that it sheds light on an organization that makes every effort to be compliant with all State and Federal laws, rules and regulations.

As always, should you have any questions, please do not hesitate to contact me. You may e-mail me at asnow@genrx2u.com or reach my direct line at (602) 892-4250 x 2012.

Kind regards,

Allyson L. Snow

Allyson L. Snow, J.D.
General Counsel
GenRx Pharmacy

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

November 05, 2018

GENRX PHARMACY, A GENRX COMPANY
ATTN: SHANNA DIAZ, PIC
17250 N HARTFORD DR STE 115
SCOTTSDALE, AZ 85255

RE: CI 2018 81733
GENRX PHARMACY, A GENRX COMPANY
NRP 1928

The attached Citation CI 2018 81733, has been issued to GENRX PHARMACY, A GENRX COMPANY, NRP 1928. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2018 81733	GENRX PHARMACY, A GENRX COMPANY, NRP 1928

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4112 subd. (c)	Nonresident pharmacies must report any change of corporate officers	$500.00
Bus. & Prof. Code § 4120 subd. (a)	Nonresident Pharmacy: Registration Required	$500.00
CCR, Title 16, § 1709 subd. (a)	Names of Owners and Pharmacist in Charge; Each permit to operate a pharmacy shall show the name and address of the pharmacy, the form of ownership, the pharmacist in charge and the names of all owners and the names of the corporate officers (if a corporation). Any changes must be reported to the Board in writing within 30 days	Citation without a fine
CCR, Title 16, § 1709 subd. (b)	Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity... Shall require written notification to the board within 30 days	Citation without a fine

CONDUCT:

Business and Professions Code section 4112(c) requires a nonresident pharmacy to report any change of corporate officers to the Board. Specifically, on November 4, 2015 and February 29, 2016, GenRx Pharmacy changed their corporate officers and failed to notify the Board within 30 days. GenRx Pharmacy notified the Board approximately 411 and 294 days after the changes occurred.

Business and Professions Code section 4120(a) requires a nonresident pharmacy to obtain a license from the Board prior to selling or distributing dangerous drugs or devices in California. On or about April 7, 2015, GenRx Pharmacy changed locations and operated with an invalid license number for approximately 696 days until their change of location application was approved.

California Code of Regulations section 1709(a) requires any changes in the pharmacist-in-charge, or owners, or corporate officers to be reported to the Board within 30 days. Specifically, on November 4, 2015 and February 29, 2016, GenRx Pharmacy changed their corporate officers and failed to notify the Board of the changes within 30 days. GenRx Pharmacy notified the Board approximately 411 and 294 days after the changes occurred.

California Code of Regulations section 1709(b) requires any transfer of 10 percent or more of the beneficial interest in a business entity licensed by the Board, to a person or entity who did not have a beneficial interest at the time the original license was issued, be reported to the Board within 30 days. Specifically, on or about August 4, 2015, GenRx Corp. reorganized their corporate ownership by inserting two new entities who were previously not affiliated with the license. GenRx Corp. failed to notify the Board of these changes until December 19, 2016, approximately 503 days later.

COPY

CITATION ISSUED ON: November 05, 2018	TOTAL AMOUNT OF FINE(S): $1,000.00
PAYMENT OF FINE(S) DUE BY: December 05, 2018	

Rec'd 11/15/19

Rev 12/2018
Citation Hearing Order

BEFORE THE DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
OF THE DEPARTMENT OF COMMERCE OF THE STATE OF UTAH
Heber M. Wells Building, 160 East 300 South, Salt Lake City, Utah
Mailing Address: DOPL, Attn: Citations, PO Box 146741, SLC, UT 84114-6741
Telephone: (801) 530-6628; Fax (801)530-6511

IN THE MATTER OF THE CITATION NUMBER 100556

ISSUED TO ("RESPONDENT") GenRx Pharmacy

THE ABOVE MATTER
- ☐ CAME ON FOR HEARING ON THE _____ DAY OF _____, 20____
- ☑ WAS SUBMITTED IN WRITING ON THE 17 DAY OF Oct, 20 19

BEFORE Kim Lesh, PRESIDING OFFICER.

APPEARING FOR THE DIVISION: _____ ☑ NOT APPLICABLE

APPEARING FOR THE RESPONDENT: _____ ☑ NOT APPLICABLE

☐ RESPONDENT ACKNOWLEDGES AND UNDERSTANDS THE INFORMAL CITATION HEARING INSTRUCTION FORM.
☑ NOT APPLICABLE

FINDINGS: (CHECK ITEMS THAT APPLY)
- ☑ THE CITATION IS SUPPORTED BY COMPETENT EVIDENCE.
- ☑ THE CITATION SHOULD HAVE BEEN ISSUED.
- ☑ AN ADMINISTRATIVE SANCTION IS APPROPRIATE.

DECISION: (CHECK ITEMS THAT APPLY)
- ☐ THE CITATION IS AFFIRMED
- ☐ THE CITATION IS DISMISSED
- ☑ THE CITATION IS MODIFIED AS FOLLOWS: fine reduced

ORDER: (CHECK ITEMS THAT APPLY)
- ☑ THE RESPONDENT IS ORDERED TO PAY A FINE IN THE AMOUNT OF $ 200 AS FOLLOWS: Paid $300 on 10/17/19. $100 refund in 2 mos.

**********IF ANY AMOUNT IS NOT PAID WHEN DUE, THE MAXIMUM FINE PERMITTED BY STATUTE IN THE AMOUNT OF $_____ BECOMES DUE AND PAYABLE IMMEDIATELY**********

- ☑ THE RESPONDENT IS ORDERED TO CEASE AND DESIST FROM: (SUMMARY ONLY. SEE CITATION FOR STATUTE OR RULE)
  - ☐ ENGAGING IN OR REPRESENTING ONESELF TO BE ENGAGED IN A REGULATED PROFESSION OR TRADE WHILE NOT LICENSED OR EXCEPTED FROM LICENSURE.
  - ☐ ACTING IN A REGULATED PROFESSION OR TRADE BEYOND THE SCOPE OF THE LICENSE HELD.
  - ☐ HIRING OR AIDING AND ABETTING THE UNLICENSED ACTIVITY OF PERSONS OR ENTITIES WHO ARE REQUIRED TO BE LICENSED; OR KNOWINGLY EMPLOYING A PERSON WHO IS REQUIRED TO BE LICENSED BUT IS NOT.
  - ☑ OTHER failing to report adverse action

REASON(S) FOR DECISION AND ORDER:
- ☑ RESPONDENT ADMITTED COMMITTING THE OFFENSE IN THE NOTICE OF RESPONSE AND/OR AT THE HEARING.
- ☐ RESPONDENT DENIED COMMITTING THE OFFENSE BUT THE DIVISION ESTABLISHED A PRIMA FACIA CASE.
- ☐ RESPONDENT DID NOT APPEAR AND A DEFAULT WAS ENTERED AGAINST HIM.
- ☑ THERE WAS SUFFICIENT EVIDENCE PRESENTED OF MITIGATING OR AGGRAVATING CIRCUMSTANCES OR OTHER GOOD CAUSE TO MODIFY THE STANDARD FINE.
- ☑ A CEASE AND DESIST ORDER IS WARRANTED TO PREVENT CONTINUED UNLAWFUL CONDUCT.
- ☐ CITATION IS FINAL. THE DEADLINE TO CONTEST THE CITATION HAS PASSED.

EXPLANATION: Reduced.

☐ EXPLANATION continued on next page

****

THIS IS A FINAL ORDER ON THE MATTER. ANY PERSON OR ENTITY WHO FAILS TO COMPLY WITH A FINAL ORDER OF THE DIVISION MAY BE FOUND GUILTY OF A CLASS A MISDEMEANOR AND THE DIVISION MAY REFUSE TO ISSUE OR RENEW OR MAY SUSPEND, REVOKE, OR PLACE ON PROBATION A LICENSE YOU HOLD OR APPLY FOR.

Agency review of this order may be obtained by filing a written request for agency review with the Executive Director of the Department of Commerce within thirty (30) days after the issuance of this order. Any such request must comply with the requirements of Utah Code §63G-4-301 and Utah Admin. Code R151-4-902.

If a DEFAULT order was issued, there are no agency review rights, only motion to set aside--please see the attached "Notice".

DATED THIS 12 DAY OF Nov, 20 19

Kim Lesh
PRESIDING OFFICER

☐ A COPY OF THIS ORDER WAS PROVIDED TO RESPONDENT AT THE HEARING.
☑ A COPY OF THIS ORDER WAS MAILED TO RESPONDENT ON THE 12 DAY OF Nov 20 19

INFORMATION ABOUT AGENCY REVIEW

Department of Commerce
160 East 300 South, Box 146701
Salt Lake City, UT 84114-6701

If you have been denied a license, received disciplinary action on your license, lost a citation hearing, or have otherwise been adversely impacted by a decision from one of the Divisions at the Department of Commerce, please be aware that you may request agency review of that decision by the Department's Executive Director. Upon review, the Executive Director could uphold, reverse, or modify the Division's decision, or might return the case to the Division for further consideration.

If you choose to file a request for agency review, please keep in mind all of the following:

- **Written Request and Due date:** Your request for agency review ("Request") must be received **no later than 30 days** from the date of the Division order that you wish reviewed. The Request must be in writing and must be addressed to the **Executive Director, Utah Department of Commerce**, at the above address;
- **Copy of Order:** You must include with your Request a copy of the letter or order you wish reviewed;
- **Transcript of Hearing:** If a hearing was held in your case, and you are challenging the order on the grounds that the evidence presented at the hearing did not support the order, you must, at your expense, order a transcript of the hearing and file it with the Department. You must also file with the Department your certification verifying that you have ordered a transcript of the proceeding and stating the date by which you expect to file the transcript with this Department. (You may use the form titled "Certification Regarding Transcript," accessed at: http://www.commerce.utah.gov/agencyrev.html) For instructions on how to order a transcript, you may contact the hearing officer or administrative law judge who conducted the hearing. However if the hearing involved a DOPL Citation, contact Kim Leshar at (801) 530-6628; if the hearing was before the Division of Real Estate, contact Amber Nielsen at (801) 530-6750;
- **Memorandum in Support of Your Request:** You may file a memorandum to support your Request. If you are required to file a transcript of the hearing with the Department, your memorandum must be filed no later than fifteen (15) days after the filing of the transcript. Otherwise, your memorandum must be filed at the time you file your Request;
- **Reply Memorandum:** If the Division files a response, you may file a final reply memorandum no later than ten (10) days after service of any response from the Division;
- **Basis for Request:** In order to succeed on agency review, you must be able to show that you were substantially prejudiced as a result of any of the grounds identified in Utah Code Ann. §63G-4-403; and
- **Copies to Division:** You must provide the Division copies of all documents that you file with the Department.

Please note that the Utah Administrative Procedures Act (UAPA), Utah Code Ann. Sections 63G-4-101 *et seq.*, and the Department's UAPA Rules, Utah Admin. Code R151-4-101 *et seq.*, govern requests for agency review. Nothing contained in this document supersedes the referenced statutes and rules. You may access the applicable provisions at your local library or on the Department of Commerce web site: http://www.commerce.utah.gov/agencyrev.html.

If you have any questions about how to proceed, you are encouraged to seek legal advice from an attorney. You may contact Masuda Medcalf, Administrative Law Judge, at (801) 530-7663, with any technical or procedural questions, but the merits of the case cannot be discussed.

Revision Date: September 13, 2018

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

GENRX PHARMACY
17250 N HARTFORD DR STE 115
SCOTTSDALE AZ 85255

IN THE MATTER OF THE CITATION OF **GENRX PHARMACY**	**ORDER TO SET ASIDE PREVIOUS ORDER AND DISMISSAL** Citation No. 100556

Good cause appearing, it is hereby ordered that the November 12, 2019 Order for the above referenced citation be set aside. It is further order that the citation be dismissed without prejudice.

Dated this 31 day January, 2020.

Kim Lesh
Citation Coordinator

SEAL

I hereby certify that on the 31 day of Jan, 2020, a true and correct copy of the foregoing ORDER OF DISMISSAL was sent first class mail, postage prepaid, to the following:
Respondent

Investigator Moran

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
GENRX	)	
	)	
Non-Resident Pharmacy Permit Number: 114306	)	**CASE NO: 17-L-0057**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against GenRX which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and GenRX through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that GenRX has violated the provisions of law based upon the conduct set out in all Counts of the Statement.

2. GenRX shall pay an administrative fine in the amount of Ten Thousand Dollars ($10,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. GenRX expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975),

§34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. GenRX further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, GenRX hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. GenRX acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against GenRX' permit, including, but not limited to revocation.

6. GenRX acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. GenRX acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 10th of December, 2019.

GENRX

BY: _____

ITS: President

_____

Spencer Larche, Attorney for GenRX

DONE this the 17th of December, 2019.

ALABAMA STATE BOARD OF PHARMACY

By: _____

Kenny Sanders, R.Ph., President

By: _____

James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
GENRX	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy	)	**CASE NO: 17-L-0057**
Permit Number: 114306	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: GENRX
17250 North Hartford Drive
Suite 115
Scottsdale, Arizona 85255

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on September 17, 2019 at 1:00 p.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate GENRX should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that GENRX has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the Kentucky State Board of Pharmacy issuing a fine for delivering prescription orders to patients in Kentucky without a permit/license to do so as more fully set out in the May 4, 2017 letter to the Board from you attached hereto as Exhibit "A".

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Stipulation and Consent Order by the Minnesota Board of Pharmacy on July 11, 2018 attached hereto as Exhibit "B" and/or based upon your dispensing of prescriptions into the State of Minnesota without a license to do so as more fully set out in the above referenced Order.

COUNT FOUR

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count Three above.

COUNT FIVE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Pre-Charge Consent Order by the Maryland Board of Pharmacy on December 7, 2018 attached hereto as Exhibit "C" and/or dispensing Seven Thousand Three Hundred Fifty-Four (7,354) prescriptions into Maryland without a permit to do so.

COUNT SIX

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count Five above

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the

aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT SEVEN

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

Notice is further given that in the event you are found guilty of the allegations contained in any or all of the preceding Counts contained in this Statement of Charges and Notice of Hearing, the Board may consider in assessing punishment the Consent Orders entered by the Board on November 2, 2016 and/or February 8, 2017, said documents being attached hereto and made a part hereof as Exhibits "D" and "E" respectively.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 13th day of May, 2019.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

State of Vermont
Office of the Secretary of State

Office of Professional Regulation
89 Main Street, 3rd Floor
Montpelier, VT 05620-3402
sos.vermont.gov

James C. Condos, Secretary of State
Christopher D. Winters, Deputy Secretary
S. Lauren Hibbert, Director

December 2, 2020

GenRX
Attn: Allyson Snow, Esq.
17250 N. Hartford Dr.
Scottsdale, AZ 85255

CASE: In Re GenRx
Credential: 036.0123163
Docket No.: 2020-82

Dear Attorney Snow:

Enclosed please find a copy of the approved *Stipulation and Consent Order*

For questions about complying with this Order, please contact the Case Manager at 802-828-2875

Sincerely,

E-SIGNED by S. Lauren Hibbert
on 2020-12-02 15:21:15 EST

S. Lauren Hibbert
Director

Enc: *Stipulation and Consent Order*

cc: Stephen Reynes, Esq., Hearing Officer
Elizabeth St. James, Esq., Prosecuting Attorney
Carla Preston, Case Manager
Allyson Snow, Esq., Attorney for Respondent, First Class Mail, Email

VERMONT

DocuSign Envelope ID: 5090FCD7-E805-4E3C-9EA3-2CBCF8BE8BEB

STATE OF VERMONT
SECRETARY OF STATE
OFFICE OF PROFESSIONAL REGULATION
BOARD OF PHARMACY

IN RE:	)	
GENRX PHARMACY	)	**Docket No. 2020-82**
License No.: 036.0123163	)	

STIPULATION AND CONSENT ORDER

STIPULATION

NOW COMES the State of Vermont, by and through State Prosecuting Attorney Elizabeth A. St. James, and the respondent in this matter, GenRX, who stipulate and agree as follows:

Board Authority

1. The Vermont State Board of Pharmacy (the "Board") has authority to issue warnings or reprimands; suspend, revoke, limit, or condition current licenses; or prevent the renewal of lapsed licenses if, after disciplinary hearing, the Board finds that the Respondent has engaged in unprofessional conduct. 3 V.S.A. § 129(a); 3 V.S.A. § 129a; 3 V.S.A. § 814(d); 26 V.S.A. §2051; 26 V.S.A. §2075; 26 V.S.A. §2064; 26 V.S.A. §2041; the Administrative Rules of the Board of Pharmacy; and the Rules of the Office of Professional Regulation.

Stipulated Facts

2. GenRX Pharmacy ("Respondent") of Scottsdale, Arizona, is licensed in the State of Vermont as a Non-Resident Pharmacy under license number 036.0123163. This license was first issued on July 29, 2016, and expires on July 31, 2021.

3. Respondent initially became licensed in the State of Vermont on July 29, 2016.

4. In April of 2016, a pharmacy benefits manager notified the Office of Professional Regulation that Respondent had dispensed prescriptions into Vermont without holding a valid Vermont license.

5. Prior to licensure, Respondent made the following twenty-three (23) separate and distinct shipments of drugs into the State of Vermont between August 2014 and May 2016:

   a. 9 shipments of sulfacleanse 8/4% suspension
   b. 6 shipments of doxycylcline hyclate 150mg tablets
   c. 8 shipments of benzepro 7% wash

6. All drugs were dispensed and shipped pursuant to patient-specific prescription orders.

7. Dispensing and shipping drugs into the State of Vermont requires a license.

Violation One: 3 V.S.A. § 127 Unauthorized Practice.

8. The State re-alleges and incorporates Paragraphs 2 through 6 above.

9. Paragraphs 2 through 6 above demonstrate that Respondent practiced the regulated profession of Pharmacy in the State of Vermont by shipping drugs into the state without obtaining the required license to do so.

10. The act(s), omission(s), and/or circumstance(s) described above constitute grounds for discipline because the Respondent has engaged in the unauthorized practice of a regulated profession, in violation of 3 V.S.A. § 127.

Violation Two: 26 VSA § 2041 Unlawful Practice

11. The State re-alleges and incorporates Paragraphs 2 through 6 above.

12. It is unlawful for any person or business entity to engage in the practice of pharmacy unless licensed to so practice.

13. Paragraphs 2 through 6 above demonstrate that Respondent engaged in the practice of pharmacy without a license to so practice.

14. The act(s), omission(s), and/or circumstance(s) described above constitute grounds for discipline because the Respondent has engaged in the unauthorized practice of a pharmacy, in violation of 26 VSA § 2041.

Understandings

15. Respondent admits that the facts above are true and that the conditions below are necessary to protect the public.

16. Respondent understands that the Board of Pharmacy must review and accept the terms of the Consent Order. If the Board rejects any portion, the entire Stipulation and Consent Order shall be null and void.

17. Respondent specifically waives any claims that any disclosures made to the full Board during its review of this agreement have prejudiced his rights to a fair and impartial hearing in future hearings if this agreement is not accepted by the Board.

18. Respondent has read and reviewed this entire document and agrees that it contains the entire agreement between the parties.

19. Respondent is not under the influence of any drugs or alcohol at the time he signs this Stipulation and Consent Order.

20. Respondent voluntarily enters into this agreement after the opportunity to consult with legal counsel and is not being coerced by anyone into signing this Stipulation and Consent Order.

21. Respondent voluntarily waives his right to a contested hearing before the Board and waives any right to appeal from this Stipulation and Consent Order.

22. Respondent agrees that the Order set forth below may be entered by the Board.

ORDER

Based on the Stipulation above, it is **ORDERED AND ADJUDGED** as follows:

A. An **ADMINISTRATIVE PENALTY OF SEVEN THOUSAND FIVE HUNDRED DOLLARS ($7,500)** is assessed against Respondent. Respondent shall remit payment within ninety (90) days of the date of entry of this Order

B. Notwithstanding any provision above, the Respondent must continue to meet all requirements for maintaining a license, license renewal, and license reinstatement.

C. This Stipulation and Consent Order is a matter of public record and may be reported to other licensing authorities as provided in 3 V.S.A. § 129(a).

D. This Stipulation and Consent Order will remain part of Respondent's licensing file and may be used for purposes of determining sanctions in any future disciplinary matter.

AGREED TO:

Dated: 12/2/20

STATE OF VERMONT
SECRETARY OF STATE

By: _____
Elizabeth A. St. James
State Prosecuting Attorney

Dated: 12/2/2020

GENRX
RESPONDENT
DocuSigned by:

By: Allyson Snow
GenRX
Authorized Agent

APPROVED AND SO ORDERED:

Dated: December 02, 2020

VERMONT BOARD OF PHARMACY

By: _____
Chairperson

Date of Entry: 12/2/2020

DocuSign Envelope ID: 6CEA9AF6-23FC-499B-8658-94937423F8DF

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
GENRX	)	
	)	
Non-Resident Pharmacy Permit Number: 114306	)	**CASE NO: 21-L-0004**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against GenRx which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and GenRx through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that GenRx has violated the provisions of law based upon the conduct set out in Counts One and Two of the Statement. Count Three of the Statement shall be dismissed with prejudice.

2. GenRx shall pay an administrative fine in the amount of Twenty Thousand Dollars ($20,000.00) as follows: Five Thousand Dollars ($5,000.00) by July 15, 2021, Five Thousand Dollars ($5,000.00) by August 15, 2021, Five Thousand Dollars ($5,000.00) by September 15, 2021 and Five Thousand Dollars by October 15, 2021. This payment shall not be subject to discharge in bankruptcy nor shall GenRx attempt to discharge the same.

3. GenRx expressly waive its rights pursuant to the Alabama Pharmacy

Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. GenRx further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, GenRx hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. GenRx acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against GenRx's permit, including, but not limited to revocation.

6. GenRx acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. GenRx acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 14th of June, 2021.

GENRX

DocuSigned by:
BY: Richard Sean Lonergan
8D974B9D6C80430...

ITS: R. Sean Lonergan, President

Jessica L. Welch, attorney for GenRx

DONE this the 15th of June, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Brenda Denson
Brenda Denson, PharmD, President

By: James S. Ward
James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: BS2501838
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			■ Long Term Care
	* Current license #: PH 03580		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: PILL Stat Rx, L.L.C. d/b/a HomeFree Pharmacy Services

Physical Address: 805 Beachway Drive

City: Indianapolis State: IN Zip: 46224

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: 317-829-0550 Toll Free # (NAC 639.708, NRS 639.23286): 888-696-9595

Fax: 317-829-0540 Contact Email: prayback@homefreerx.com

Website: https://safedose.com/

Nevada Business License # (if applicable) E0314922019-4

Supervising/Managing Pharmacist Name (NRS 639.220): Priscilla Rayback

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23976

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Priscilla Rayback	NV Pharmacist Registration #: 23976
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): AccuPax, LLC

Corporation/Organization Name: PILL Stat Rx, L.L.C. d/b/a HomeFree Pharmacy Services

Mailing Address: 4801 Olympic Park Plaza, Suite 1450

City: Louisville State: KY Zip: 40241

Telephone: 888-300-3006 Email: hello@homefreerx.com

Contact Person Name: Thomas Martin Butler

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President and Treasurer (title) for PILL Stat Rx, L.L.C. d/b/a HomeFree Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Thomas Martin Butler

Print Name of Authorized Person

Thomas Martin Butler

Original signature of Authorized Person (copies or stamps not accepted)

6-3-2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Priscilla Rayback hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for PILL Stat Rx, L.L.C. d/b/a HomeFree Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 3 day of June, 20 24

Notary Public

JOSE CHAVEZ
Notary Public - Seal
Marion County - State of Indiana
Commission Number NP0749224
My Commission Expires May 31, 2031

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomas Martin Butler

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Thomas Martin Butler — 6-3-2024

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 6/10/24	Amount: $500-ck 1000001598

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PILL STAT RX, L.L.C." IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-NINTH DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2999328 8300

SR# 20242590278

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203583111

Date: 05-29-24

Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072

Indianapolis, IN 46204

FACILITY
PILL Stat Rx L.L.C. d/b/a HomeFree Pharmacy Services
805 Beachway Drive
Indianapolis IN 46224
Phone: 3178290550
Owner:
Ownership Type:

LICENSE
License No: 60006901A
Profession: Pharmacy
License Type: Pharmacy
805 Beachway Drive
Indianapolis IN 46224
Phone: 3178290550

Inspection Type:	Pharmacy Inspection
Inspection Date:	5/17/2024
Result:	Pass

Remarks: Controls in a locked metal cabinet, RPh only with keys.No sterile or non-sterile compounding, no pharmacist immunizations. Sections of this inspection were left black because they do not apply to business model of this pharmacy. Questions regarding this isnpections, contact. Timothy Thomas Indiana board of Pharmacy 317-753-4000 tithomas@pla.IN.gov

Checklist Results
Pharmacy General Information
Absence of Pharmacist
Staff/Personnel
Pharmacy Equipment/Security
References
Automated Medication Systems & Automatic Counting
AMS Automated Packaging Systems
Drug storage/labeling/destruction
Dispensing/Records Retention
Fax/e-prescribing/Transfers
Remote Order Entry and Centralized Processing
Generic Substitution
Controlled Substances
DEA Forms
INSPECT
Sterile Compounding: Policies and Procedures
Sterile Compounding: Engineering Controls
Sterile Compounding: Personnel
Sterile Compounding: Labeling/Documentation
Non-sterile Compounding
Remote Locations (Type II only)

Emergency Drug Kits/Crash Carts
Quality-Related Events/Patient Own Medications
Special Medications
Immunization Rule
Patient Confidentiality (HIPAA)
Prescription Audit

As the undersigned representative of the licensee, I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as, or on behalf of the licensee.

The alleged violator has voluntarily entered into an Opportunity to Correct Plan with the Indiana Professional Licensing Agency (PLA). Pursuant to IC 4-21.5-2.5-7, the alleged violator enters into a written Corrective Plan to correct the alleged violation(s) set forth above before the agency institutes an enforcement action which may include the filing of a Consumer Complaint with the Office of the Indiana Attorney General. Upon notice that the alleged violation(s) has been corrected, this Agency shall re-inspect not more than thirty (30) days after to determine if you have substantially complied with the applicable rule or state statute. If subsequent inspection identifies a failure to address previous violations the facility will "fail" the inspection and additional enforcement actions may be initiated against licensure.

In order to avoid additional enforcement action, the alleged violator must submit the Corrective Plan within five (5) business days after the initial inspection. A plan of corrective action can be either emailed to PLACompliance@pla.in.gov, or mailed to: Indiana Professional Licensing Agency, Attn: Compliance Division, 402 W. Washington St. RM W072, Indianapolis, IN 46204.



5/17/2024 11:50:17 AM



Signature of Inspector | Date/Time | Signature of Owner/Representative

STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
Fax: (317) 233-4236

Official Proof of Licensure
Digitally Certified Record

Personal Information

Facility Name:	PILL Stat Rx L.L.C. d/b/a HomeFree Pharmacy Services
Address:	805 Beachway Drive Indianapolis, IN 46224
Owner Name:	

License Information

Number Issued:	60006901A
License Type:	Pharmacy - Closed Door (III)
Status:	Active
Issue date:	10/30/2023
Expiration Date:	12/31/2025
Obtained By:	Change of Ownership

This licensee has met ALL requirements for licensure in the State of Indiana - including successfully passing all required exams.

For disciplinary action information, please visit our License Search & Verify service at www.in.gov/pla/3119.htm. Disciplinary action will either show under Previous Action or Violations. For additional information including questions regarding Disciplinary Action, contact the appropriate Board or Commission at http://www.in.gov/pla/boards.htm.

Digitally Certified on: Mon Oct 30 04:19:09 PM EST 2023

STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
Fax: (317) 233-4236

Digitally Certified Proof of Licensure

RE: PILL Stat Rx L.L.C. d/b/a HomeFree Pharmacy Services

I, Lindsay M. Hyer, Executive Director of the Indiana Professional Licensing Agency and custodian of the records therein, hereby certify that the attached is the digitally certified proof of licensure, as requested, and as it appears in the files of the Indiana Professional Licensing Agency on the date/time certified.

This digital certification follows the requirements of Indiana's Electronic Digital Signature Act (Indiana Code 5-24-1-1 et seq.) and rules developed by the Indiana State Board of Accounts, 20 IAC 3-1 et seq. to establish a valid digital electronic signature.

To verify the authenticity of the digital certification as of the date and time stamp below, go to
https://secure.in.gov/apps/pla/search/verify/
and use our free web service. Simply browse to the location you saved the secure PDF document sent to you and upload to validate. You may also verify the authenticity in Adobe by ensuring the 'Certified by State of Indiana' blue ribbon displays at the top of the PDF.

Lindsay M. Hyer, Executive Director
Mon Oct 30 04:19:09 PM EST 2023

State of Indiana

DEMOGRAPHIC INFORMATION

Name: PILL Stat Rx L.L.C. d/b/a HomeFree Pharmacy Services

ADDRESS INFORMATION

Line 1: 805 Beachway Drive
Line 2:
City/State/Zip: Indianapolis IN 46224
County: Marion

LICENSE INFORMATION

Lic #: 60006901A
Status: Active
Method: Change of Ownership
Profession: Pharmacy Board
Issued: 10/30/2023
Type: Pharmacy
Expiration: 12/31/2025
Secondary: Closed Door (III)

DISCIPLINE INFORMATION

RELATED LICENSES

Lic #: 60006901B
License Type: CSR-Pharmacy
Name: PILL Stat Rx L.L.C. d/b/a HomeFree Pharmacy Services
License Status: Active
Relationship: Same Licensee

SPECIALTY INFORMATION

No Specialty Information

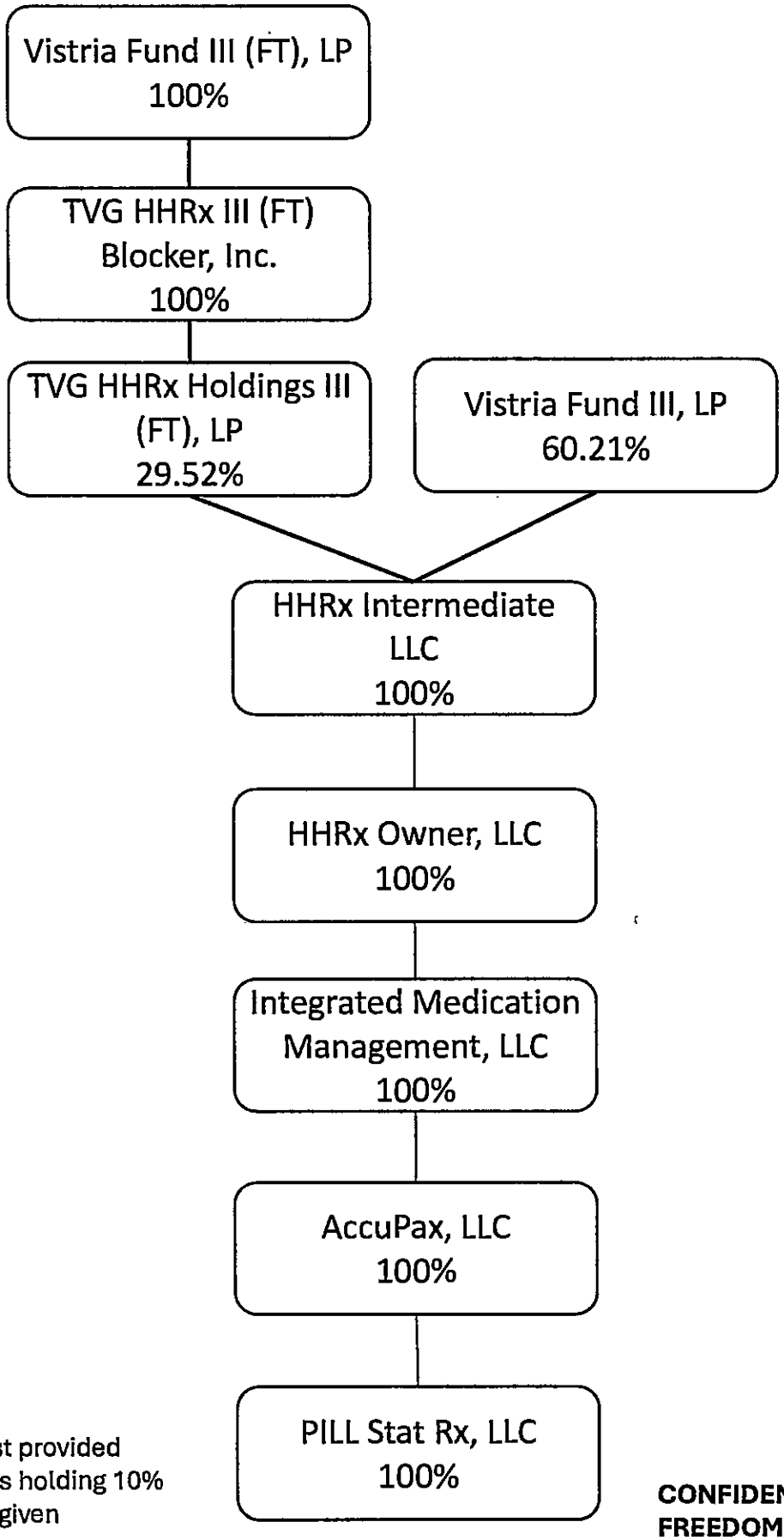
INSPECTION INFORMATION

Inspection Type: Pharmacy Inspection Report
Inspection Date: 5/17/2024
Inspection Grade: Pass

Officers as of 7/1/24

John Figueroa - Chief Executive Officer and President
Brian Adams - Vice President and Secretary
Thomas Martin Butler - Vice President and Treasurer

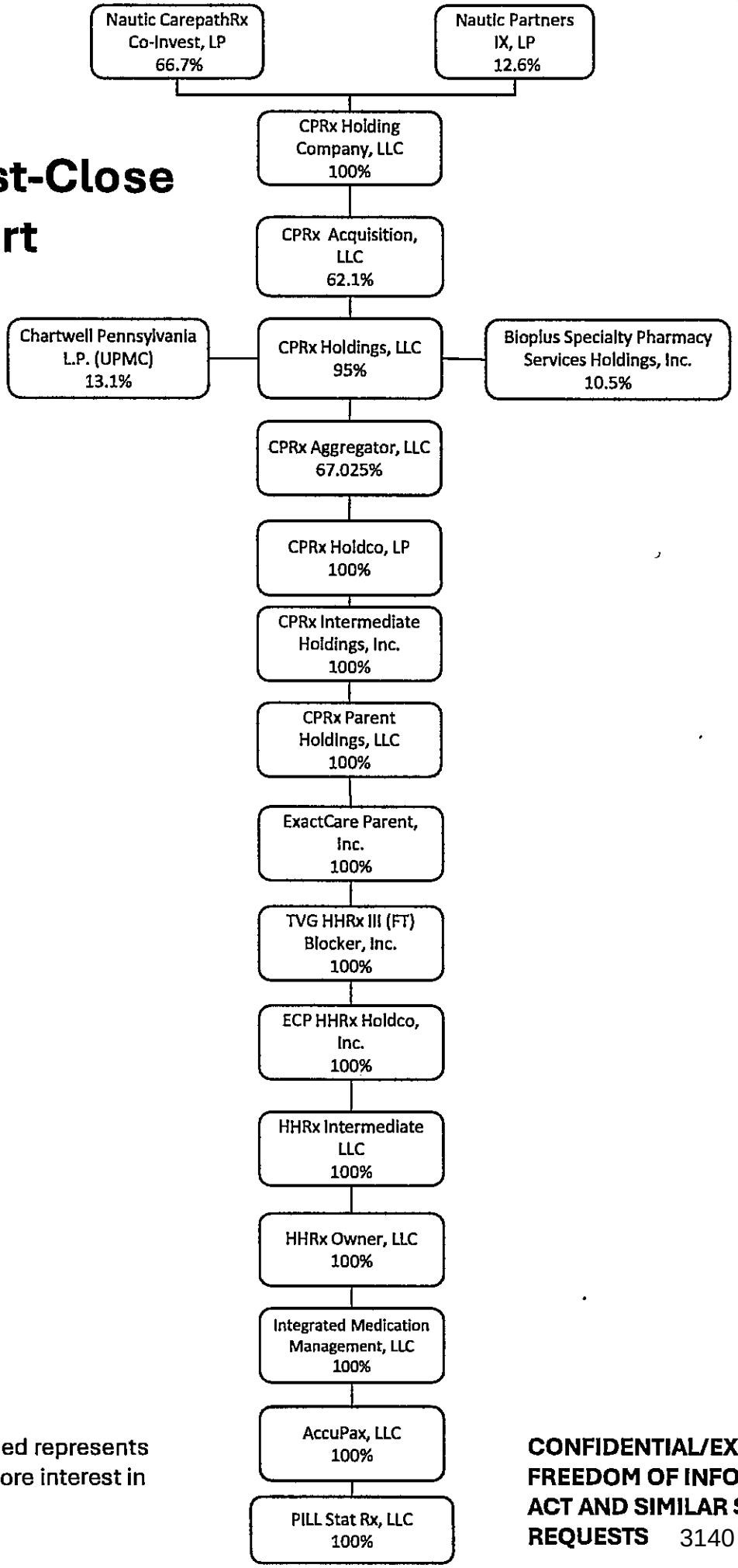
HomeFree Pre-Close Org Chart



All ownership interest provided represents all entities holding 10% or more interest in a given subsidiary.

CONFIDENTIAL/EXEMPT FROM FREEDOM OF INFORMATION ACT AND SIMILAR STATE REQUESTS

HomeFree Post-Close Org Chart



All ownership interest provided represents all entities holding 10% or more interest in a given subsidiary.

CONFIDENTIAL/EXEMPT FROM FREEDOM OF INFORMATION ACT AND SIMILAR STATE REQUESTS 3140

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PILL Stat Rx, L.L.C dba HomeFree Pharmacy Services

Pharmacy/Wholesaler License # (if applicable) PH03580

Physical Address 805 Beachway Drive

City Indianpolis State IN Zip 46224

Mailing Address (if different from physical address) N/A

City _____ State _____ Zip _____

Telephone 317-829-0550 Website https://safedose.com/

Licensing Company Email prayback@homefreerx.com

Section 2: Personal Information

First Priscilla Middle _____ Last Rayback

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Squanto Dr

City Morgantown State IN Zip 46160

Telephone [redacted] Email prayback@homefreerx.co

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Purdue University		08/92-05/98	
Address	**City**	**State**	**Zip**
610 Purdue Mall	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Arlington High School		1/90-6/92	
Address	**City**	**State**	**Zip**
1157 State Rte 55	Lagrangeville	NY	12540
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Alexander M Patch American High School		1/86-12-89	
Address	**City**	**State**	**Zip**
	Stuttgart, Germany		
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/04-present	[redacted]Squanto Dr	Morgantown	IN	46160
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Pill Stat Rx, LLC dba HomeFree Pharmacy Services			12/23-present	
Business Address		**City**	**State**	**Zip**
805 Beachway Dr		Indianapolis	IN	46224
Phone	**Title**		**Number of Employed Hours**	
317-829-0550	Pharmacy Manager		960	
Description of Duties				
Verification of prescriptions, dispensing of prescriptions, DUR, supervision of other pharmacists and technicians				

Business Name			From - To (MM/YY – MM/YY)	
Pill Stat Rx, LLC dba SafeDose Pharmacy			06/14-12/23	
Business Address		**City**	**State**	**Zip**
805 Beachway Dr		Indianapolis	IN	46224
Phone	**Title**		**Number of Employed Hours**	
317-829-0550	Pharmacy Manager		19,680	
Description of Duties				
Verification of prescriptions, dispensing of prescriptions, DUR, supervision of other pharmacists and technicians				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Priscilla Rayback, **certify that as the designated representative for**

PILL Stat Rx, LLC dba HomeFree Pharmacy Services,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PAR I am at least 21 years of age;
3. PAR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PAR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PAR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PAR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PAR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Priscilla Rayback

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/28/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Priscilla Rayback

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/30/24

Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Marion

I, Priscilla Rayback, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/30/24

Date

Subscribed and Sworn to before me this 30 day of May 2024

Notary Public Signature

JOSE CHAVEZ
Notary Public - Seal
Marion County - State of Indiana
Commission Number NP0749224
My Commission Expires May 31, 2031

(Seal)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BS2501838	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-04-2024

PILL STAT RX, LLC
DBA: HOMEFREE PHARMACY SERVICES
805 BEACHWAY DR
INDIANAPOLIS, IN 462247788

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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2,2N,3, 3N,4,5	RETAIL PHARMACY	03-04-2024

PILL STAT RX, LLC
DBA: HOMEFREE PHARMACY SERVICES
805 BEACHWAY DR
INDIANAPOLIS, IN 462247788

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ImprimisRx Nashville, LLC

Physical Address: 658 Grassmere Park, Ste 104

City: Nashville State: TN Zip: 37211

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 844-446-6979 Toll Free # (NAC 639.708, NRS 639.23286): 844-446-6979

Fax: 855-405-4669 Contact Email: Imprimisrxtn@harrowinc.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Roger Shaw Jr

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21928

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Roger Shaw Jr	NV Pharmacist Registration #: 21928
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Harrow, Inc

Corporation Name:

Mailing Address: 102 Woodmont Blvd, Ste 610

City: Nashville State: TN Zip: 37205

Telephone: 615-733-4730 Email: bburrell@harrowinc.com

Contact Person Name: Brett Burrell

Date of SEC Registration: 7-21-2006 | SEC Registration Number: 333-135970 | Stock Exchange Symbol: HROW

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☒ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacy Manager (title) for ImprimisRx Nashville, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Roger Shaw Jr.

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6-10-24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Roger Shaw Jr hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Manager (title) for ImprimisRx Nashville, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of June, 2024

Seth Salyers
Notary Public

SETH SALYERS
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF DAVIDSON
MY COMM. EXP. JULY 7, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roger Shaw Jr.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6.3.24

Date

Board Use Only	Date Received: _____	Amount: 500.00 / CC

55785

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

ID NUMBER: 0000007592
EXPIRATION DATE: 05/31/2025

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
PHARMACY
IMPRIMISRX NASHVILLE, LLC

COMMISSIONER OF HEALTH

IMPRIMISRX NASHVILLE, LLC
658 GRASSMERE PARK
SUITE 104
NASHVILLE TN 37211

13405355
55785

State of Tennessee
Department of Health

BOARD OF PHARMACY
PHARMACY
IMPRIMISRX NASHVILLE, LLC
658 GRASSMERE PARK
SUITE 104
NASHVILLE TN 37211

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000007592
EXPIRATION DATE: 05/31/2025

Jennifer L. Rothaus, Esq
ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER, DEPARTMENT OF HEALTH

DCF171

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "IMPRIMISRX NASHVILLE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF DECEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "IMPRIMISRX NASHVILLE, LLC" WAS FORMED ON THE THIRTEENTH DAY OF FEBRUARY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

7293513 8300

SR# 20234273666

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204857923

Date: 12-19-23

PHARMACY	
ImprimisRx Nashville LLC	
STREET	
658 Grassmere Park Suite 104	
CITY	ZIP
Nashville	37211
DATE OPENED	TELEPHONE NO.
	(844) 446 6977
LICENSE NO.	EXPIRY DATE
New	
DEA NO.	EXPIRY DATE
PHARMACIST IN CHARGE/Duty	LIC NO. / EXPIRY DATE
Kayla Hall	41737 / 10/31/2023

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

Inspected by	Date
Andrea Muller/Shannon Volk	4/25/2023

This inspection Satisfactory Yes ☒ No ☐

☒ Opening ☒ Relocation
☐ New Ownership ☐ Follow-up
☐ Counseling Compliance
☐ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
		1. Appropriate identification/Name Tags
		2. D. Ph./Tech ration
		3. Personnel/apparel clean
		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
		5. Certificates Displayed
		6. RX Dept. – Sufficient Space/Counseling
		7. Fully enclosed when applicable
		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
		9. Dispensing area clean, orderly, well lighted
		10. Sink, hot and cold water
		11. Refrigeration
		12. References, periodicals
		13. Vials and closures (child-proof)
		14. Shelves and drug stock clean
		15. Drugs in-date
		16. Labels correct on repackaging
		17. Legend drugs stored in RX Dept.
		18. Syringes/insulin, restricted products non-accessible

Pharmacy Hours	M-F 8-5

Compliance Yes	Compliance No	
		19. RXs numerically filed
		☐ All C's together ☐ C-11's separate ☐ Multiple file method
		20. Patients identifiable
		21. Prescribers identifiable
		22. New verbal RXs initialed by appropriate personnel
		23. Date of original dispensing
		24. Initials of dispensing D.Ph.
		25. Quantity dispensed indicated
		26. Appropriate Emergency C-11 RXs
		27. Computer labels applied appropriately to RXs
		28. Pharmacist Signature Log
		29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
		30. Authorization documented on Rx
		31. Manufacturer indicated on Rx or System
		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
		33. Patient profiles
		34. Drug Utilization Review
		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
		36. Readily retrievable
		37. All C-11 records separate
		38. DEA Form 222 Copy 3 on hand & completed
		39. Drug Receipt date on invoices
		40. Record of drug transfers
		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
		42. Last DEA Inventory (date)
		42. Last Theft/loss report (date)
		43. Access to Control Substance Monitoring Database

Andrea.Muller@tn.gov

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** YES ☐ NO ☐

Immediately
Needs Improvement
Within 30 Days

Remarks or Recommendations: Maintain DEA, Perform adequate control substance inventory. Sign dated and need on file; Pharmacist aware to review here

I _____ hereby acknowledge and understand all notations made on this report; and confirm that
(Pharmacist Signature)
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

PH-4031 REV 01/18

RDA SW-30

Harrow Officers and Directors

- Officers
  - Mark L. Baum – Chief Executive Officer
  - Andrew Boll – Chief Financial Officer
  - John Saharek – Chief Commercial Officer
- Directors
  - Mark L. Baum
  - Marty Makary, M.D., M.P.H.
  - Teresa F. Sparks
  - Perry J. Sternberg

Harrow Top 4 Shareholders

Opaleye Management Inc. 10.88%

Private Capital Management 10.34%

Mark Baum 5.78%

Daniel Kaufman 5.37%

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FI3434115	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N,4	RETAIL PHARMACY	09-19-2023

IMPRIMISRX NASHVILLE, LLC
658 GRASSMERE PARK
STE 104
NASHVILLE, TN 372113683

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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IMPRIMISRX NASHVILLE, LLC
658 GRASSMERE PARK
STE 104
NASHVILLE, TN 372113683

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Form DEA-223 (9/2016)

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH _____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FS6563666 ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: SPRX, Inc. dba InjuryScripts

Physical Address: 3740 Saint JOhns Bluff Road South Suite 21

City: Jacksonville State: FL Zip: 32224

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 904-575-3571 Toll Free # (NAC 639.708, NRS 639.23286): 844-426-6779

Fax: 844-904-2667 Contact Email: compliance@injuryscripts.com

Website: www.injuryscripts.com

Nevada Business License # (if applicable) NV20161379498

Supervising/Managing Pharmacist Name (NRS 639.220): Tiffany McGraw

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21270

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Tiffany McGraw	NV Pharmacist Registration #: 21270
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	✓	

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: William Scrogins	Credentials: PS22535	%: 50
Name: Gregory Balotin	Credentials: PS33362	%: 50
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): None

Corporation/Organization Name: SPRX, Inc.

Mailing Address: 3740 Saint Johns Bluff Road South Suite 21

City: Jacksonville State: FL Zip: 32224

Telephone: 904-575-3571 Email: compliance@injuryscripts.com

Contact Person Name: Kara McHugh

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CFO (title) for SPRX, Inc. dba InjuryScripts (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Gregory Balotin

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/14/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Gregory Balotin hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CFO (title) for SPRX, Inc. dba InjuryScripts (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 14th day of June, 2024

Kara M'Hugh
Notary Public

My commission expires: 03-22-2028

KARA MCHUGH
MY COMMISSION # HH 467135
EXPIRES: March 22, 2028

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gregory Balotin

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6/14/2024

Date

Board Use Only	Date Received: 6/24/24	Amount: $500-ck 1163

State of Florida
Department of State

I certify from the records of this office that SPRX, INC. is a corporation organized under the laws of the State of Florida, filed on January 8, 2016.

The document number of this corporation is P16000002044.

I further certify that said corporation has paid all fees due this office through December 31, 2024, that its most recent annual report/uniform business report was filed on April 16, 2024, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twelfth day of June, 2024

Secretary of State

Tracking Number: 7603366973CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 23433
Insp # 173752

NAME	PERMIT NUMBER	DATE OF INSPECTION
SPRX, INC	29929	12/13/2022
DOING BUSINESS AS		
INJURYSCRIPTS		
STREET ADDRESS	**TELEPHONE #**	**EXT**
3740 SAINT JOHNS BLUFF ROAD S. SUITE 21	904-477-9054	
CITY	**COUNTY**	**STATE/ZIP**
JACKSONVILLE	DUVAL	FL/32224

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9 AM to 5 PM
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	Monday Hours 9-5
Tuesday Hours 9-=5	Wednesday Hours 9-5
Thursday Hours 9-5	Friday Hours 9-5
Saturday Hours closed	Sunday Hours closed

Registered Pharmacist / Intern / Tech

License # 54897	Licensee Name Sandy Acosta
License Type Pharmacy Tech	
License # 25661	Licensee Name Cindy Sambito
License Type Pharmacy Tech	
License # 55202	Licensee Name Andrew York
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FS6563666	

License Relations

Pharmacy Affiliate

BALOTIN, GREGORY HARPER	License #
SCROGINS, WILLIAM C	License #

RX DPT MGR/COR/POR

MCGRAW, TIFFANY LYNN	License # 55519

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.]	Yes
A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.]	Yes

Patient Consultation Area sign is posted. [64B16-30.003, F.A.C]	Yes

Community Requirements General Section

Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	Yes
Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.].	Yes
Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.]	Yes
Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.]	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes

Additional Community Requirements

Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.]	Yes
Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]	Yes
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	Yes
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(i) F.S.]	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	Yes
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.]	Yes
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11]	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	Yes
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	Yes
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]	Yes
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	Yes
Compounding records properly maintained. [64B16-28.140(4), F.A.C.]	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]	N/A
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.]	N/A
Pharmacist has a written collaborative practice agreement. [465.1865, F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S]	N/A

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]

INV359 - Community Requirements

SPRX, INC

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The originating pharmacy is identified with pharmacy name and address on the prescription container label.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

I have read end have hed this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

HAYES, FRANK

Frank Hayes

Date:12/13/2022

Representative:

Andrew York

Andrew York

Date:12/13/2022

AC# 11323631

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/24/2022	PH 29929	132021

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

QUALIFICATION(S):
Community Pharmacy

Expiration Date: **FEBRUARY 28, 2025**
SPRX, INC
InjuryScripts
3740 ST. JOHNS BLUFF RD S.
STE 21
JACKSONVILLE, 32224

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

June 19, 2024

Sprx, Inc. Dba Injuryscripts
3740 St Johns Bluff Rd S Ste 21
Jacksonville, FL 32224

RE: License Certification for Sprx, Inc

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH29929
ORIGINAL CERTIFICATION:	03/02/2016
EXPIRATION DATE:	02/28/2025
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No
LICENSE GRANTED BY:	N/A
OTHER CERTIFICATIONS:	Community Pharmacy, Schedule Ii & Iii

To expedite the verification process, the above format is the standard format for all license certifications. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gwendolyn B. Freeman

Gwendolyn B. Freeman
Operations and Management Consultant Manager

[redacted]

Owner/Officers

Gregory Balotin, PharmD
CFO, Director
[redacted] Harbour View Drive
Ponte Vedra Beach, FL 32082
FL License: PS33362
[redacted]
50% Owner

William Scrogins, RPh
COO, Director
[redacted] Beach Avenue
Atlantic Beach, FL 32233
FL License: PS22535
[redacted]
50% Owner

SHAREHOLDERS

SPRX, INC.

CERT NO.	ISSUED TO	SHARES	DATE ISSUED
1	William C. Scrogins	100	January 8, 2016
2	Gregory Balotin	100	January 8, 2016

AUTHORIZED TO ISSUE: 5,000 Shares Common Stock
ISSUED:
100 Shares Par Value $1.00 Each Common Stock
100 Shares Par Value $1.00 Each Common Stock

1/26/2016 12:39 PM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: SPRX, Inc. dba InjuryScripts

Pharmacy/Wholesaler License # (if applicable): PH29929

Physical Address: 3740 Saint Johns Bluff Road South Suite 21

City: Jacksonville State: FL Zip: 32224

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 904-575-3571 Website: www.injuryscripts.com

Licensing Company Email: compliance@injuryscripts.com

Section 2: Personal Information

First: Tiffany Middle: Lynn Last: McGraw

Alias(es, nicknames, name changes, etc.): Lovelace

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]Lorijane Lane

City: Saint Johns State: FL Zip: 32259

Telephon[redacted] Email: tiffany.mcgraw@injuryscripts.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Lake Erie College of Osteopathic Medicine (LECOM)		08/12- 06/16	
Address	**City**	**State**	**Zip**
5000 Lakewood Ranch Blvd.	Bradenton	FL	34211
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Florida State College at Jacksonville		08/10-05/12	
Address	**City**	**State**	**Zip**
11901 Beach Blvd.	Jacksonville	FL	32246
Diploma/Degree obtained, if any			
Associate in Arts			

School Name		From - To (MM/YY – MM/YY)	
Bishop Kenny High School		08/06-05/09	
Address	**City**	**State**	**Zip**
1055 Kingman Ave.	Jacksonville	FL	32207
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/17- Current	[redacted] Lorijane Lane	St Johns	FL	32259
06/16- 07/17	[redacted] Founders Cove	Jacksonville	FL	32225
07/14-16/16	[redacted] Willow Beck Ln #107	Bradenton	FL	34202

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
SPRX, Inc.			06/17- Current
Business Address	**City**	**State**	**Zip**
3740 Saint Johns Bluff Road South Suite 21	Jacksonville	FL	32224
Phone	**Title**		**Number of Employed Hours**
904-575-3571	Pharmacist in Charge		13,000
Description of Duties			
Securing prescription department, counseling patients, dispensing prescription orders, oversee drug ordering, overseeing technicians.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

The pharmacy has voluntarily relinquished a few out of state permits due to the lack of patients being serviced in that state. Licenses that were voluntarily relinquished or allowed to lapse are: AK, ID, IA, KS, MT, NE, NV, WA

Tiffany McGhee

Original Signature (electronic, copies or stamps not accepted)

6/14/2024

Date

I, Tiffany McGraw, **certify that as the designated representative for**

SPRX, Inc. dba InjuryScripts,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Tiffany McGraw

Print Name (First, Last)

Tiffany McGraw

Original Signature (electronic, copies or stamps not accepted)

6/14/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany McGraw

Print Name (First, Last)

Tiffany McGraw

Original Signature (electronic, copies or stamps not accepted)

6/14/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Duval

I, Tiffany McGraw, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Tiffany McGraw

Original Signature

6/14/2024

Date

Subscribed and Sworn to before me this 14th day of June.

Kara M'Hugh

Notary Public Signature

My Commission expires: 03-22-2028

KARA MCHUGH
MY COMMISSION # HH 467135
EXPIRES: March 22, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: SPRX, Inc. dba InjuryScripts

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH29929

Physical Address: 3740 Saint Johns Bluff Road South Suite 21

City: Jacksonville State: FL Zip: 32224

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 904-575-3571 Website: www.injuryscripts.com

Licensing Company Email: compliance@injuryscripts.com

Section 2: Personal Information

First: William Middle: Cecil Last: Scrogins

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Beach Avenue

City: Atlantic Beach State: FL Zip: 32233

Telephone: [redacted] Email: bill@injuryscripts.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Florida		06/80- 12/85	
Address	City	State	Zip
201 Criser Hall	Gainesville	FL	32611
Diploma/Degree obtained, if any			
RPh			

School Name		From - To (MM/YY – MM/YY)	
Sandalwood High School		08/77- 05/80	
Address	City	State	Zip
2750 John Promenade Blvd.	Jacksonville	FL	32246
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/17- current	[redacted] Beach Avenue	Atlantic Beach	FL	32233
05/13- 05/17	[redacted] Cherokee Drive	Neptune Beach	FL	32266

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SPRX, Inc. dba InjuryScripts			06/07- current
Business Address	**City**	**State**	**Zip**
3740 St Johns Bluff Rd S Ste 21	Jacksonville	FL	32224
Phone	**Title**		
904-575-3571	COO/ Owner		
Description of Duties			
Responsible for overseeing operations of pharmacy.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6&9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

#6- In 2008, I was audited for continuing education requirements by the Board of Pharmacy. I was unable to prove 2 hours of Medication Errors for 2005-2007 licensure biennium. A hearing was held by the Board, a settlement was reached, and I was fined $500 and had to provide proof of those two hours of continuing education to the Board in addition to the hours required for the current biennium. The fine was paid and the continuing education was completed. The case was settled and the final order was issued 03/05/2009.

#9- The pharmacy has voluntarily relinquished a few out of state permits due to the lack of patients being serviced in that state. Licenses that were voluntarily relinquished or allowed to lapse are: AK, ID, IA, KS, MT, NE, NV, WA

William Scroggins
Original Signature (electronic, copies or stamps not accepted)

6-18-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Scrogins

Print Name (First, Last)

William Scrogins 6-18-2024

Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Duval

I, William Scrogins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

William Scrogins 6-18-2024

Original Signature **Date**

Subscribed and Sworn to before me this 18th day of June.

Kara McHugh

Notary Public Signature

My Commission Expires 03-22-2028

KARA MCHUGH
MY COMMISSION # HH 467135
EXPIRES: March 22, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: SPRX, Inc. dba InjuryScripts

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH29929

Physical Address: 3740 Saint Johns Bluff Road South Suite 21

City: Jacksonville State: FL Zip: 32224

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 904-575-3571 Website: www.injuryscripts.com

Licensing Company Email: compliance@injuryscripts.com

Section 2: Personal Information

First: Gregory Middle: Harper Last: Balotin

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Harbour View Drive

City: Ponte Vedra Beach State: FL Zip: 32082

Telephone: [redacted] Email: greg@injuryscripts.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Florida College of Pharmacy		06/91- 04/98	
Address	City	State	Zip
	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Wolfson High School		08/87- 05/91	
Address	City	State	Zip
7000 Powers Avenue	Jacksonville	FL	32217
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/13 - present	[redacted] Harbour View Dr	Ponte Vedra Beach	FL	32082
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
SPRX, Inc. dba InjuryScripts			06/07- present	
Business Address		**City**	**State**	**Zip**
3740 St Johns Bluff Road South STE 21		Jacksonville	FL	32224
Phone	**Title**			
904-575-3571	CFO/ Owner			
Description of Duties				
Responsible for overseeing operations of pharmacy.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

The pharmacy has voluntarily relinquished a few out of state permits due to the lack of patients being serviced in that state. Licenses that were voluntarily relinquished or allowed to lapse are: AK, ID, IA, KS, MT, NE, NV, WA

Original Signature (electronic, copies or stamps not accepted)

6/10/28
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gregory Balotin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/14/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Duval

I, Gregory Balotin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/18/24

Date

Subscribed and Sworn to before me this 18th day of June.

Kara M'Hugh

Notary Public Signature

My Commission Exp. 03-22-2028



(Seal)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS6563666	02-28-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-13-2023

SPRX, INC
DBA INJURYSCRIPTS
3740 SAINT JOHNS BLUFF RD S STE 21
JACKSONVILLE, FL 322242650

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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Form DEA-223 (9/2016)

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all that apply)	Pharmacy Type (check all that apply)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☒ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
	* Current license #:		☐ Long Term Care
	PH – –		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: MANATEE PHARMACY SERVICES, INC (DBA MANATEE DISCOUNT PHARMACY)

Physical Address: 1802 59TH STREET WEST

City: BRADENTON State: FL Zip: 34209

Mailing Address (if different from physical address): SAME

City: SAME State: SAME Zip: SAME

Telephone: 941-209-1234 Toll Free # (NAC 639.708, NRS 639.23286): 888-628-4404

Fax: 941-209-1177 Contact Email: COMPLIANCE@MDPRX.COM

Website: https://www.mygnp.com/pharmacies/manatee-discount-pharmacy-bradenton-fl-34208/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): HAMAD UDDIN NAWAZ

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): ~~N/A~~ 24249

Section 2: List the name(s) of all the registered pharmacist(s) who practice at the pharmacy who require the maintenance of records in order to be responsible for any prescription dispensed at a particular time. Persons are responsible for only those acts of the pharmacy personnel who are registered with the Board. NRS 639.238. Use a separate page if additional space is needed.

Name: HAMAD UDDIN NAWAZ	NV Pharmacist Registration #: PS 57604 (FL license)
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: Ownership Disclosure

	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Any of the owners a health professional licensed by NRS 630, 631, Advanced Practice Registered Nurse, Physician Assistant, Physical Therapist, Occupational Therapist, Clinical Social Worker, Respiratory Therapist, Podiatrist, Optometrist, Chiropractor, Dentist, Dental Hygienist, Dental Therapist, Dental Assistant, Dental Technician, Psychologist, Marriage and Family Therapist, Clinical Professional Counselor, Clinical Alcohol and Drug Abuse Counselor, Behavior Analyst, Assistant Behavior Analyst, Genetic Counselor, Perfusionist, Athletic Trainer, Audiologist, Speech Pathologist, Hearing Aid Specialist, Registered Nurse, Licensed Practical Nurse, Licensed Psychiatric Technician, Certified Nurse Practitioner, Certified Nurse Midwife, Certified Registered Nurse Anesthetist, Radiologic Technologist, Radiologic Technologist Assistant, Radiologic Technologist Practitioner, Nuclear Medicine Technologist, Radiation Therapist, Medical Dosimetrist, Medical Laboratory Director, Medical Laboratory Technician, Medical Laboratory Technologist, Cytotechnologist, Histologic Technician, Histotechnologist, Phlebotomist, Pathologists' Assistant, Polysomnographic Technologist, Polysomnographic Technologist Trainee, Polysomnographic Technologist Technician

Section 3: Limited Liability or Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Sole Proprietorship, Trade Corporation or Company

State of Incorporation/Organization: FLORIDA

Parent Company (if any): N/A

Corporation/Organization Name: MANATEE PHARMACY SERVICES, INC (DBA MANATEE DISCOUNT PHARMACY)

Mailing Address: 1802 59TH STREET WEST

City: BRADENTON State: FL Zip: 34209

Telephone: 941-209-1234 Email: COMPLIANCE@MDPRX.COM

Contact Person Name: HAMAD UDDIN NAWAZ

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Statement of Responsibility

1. I am the PRESIDENT/CEO/DIRECTOR/PIC (title) for Manatee Pharmacy Services, Inc. DBA (Manatee Discount Pharmacy) (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

HAMAD UDDIN NAWAZ

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1-15-24

Date

[redacted]

Affidavit for Pharmacy License

I, HAMAD UDDIN NAWAZ hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PRESIDENT/CEO/DIRECTOR/PIC (title) for Maestee Pharmacy Services, Inc. (DBA Maestee Discount Pharmacy) (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 16 day of January, 2024

Notary Public

Michelle Butler
Notary Public, State of Florida
My Commission Expires 06/02/2025
Commission No. HH 372993

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HAMAD UDDIN NAWAZ

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1-15-24
Date

Board Use Only	Date Received: 1/17/24	Amount: $500 - check 1426

State of Florida
Department of State

I certify from the records of this office that MANATEE PHARMACY SERVICES INC is a corporation organized under the laws of the State of Florida, filed on November 19, 2013.

The document number of this corporation is P13000093730.

I further certify that said corporation has paid all fees due this office through December 31, 2023, that its most recent annual report/uniform business report was filed on January 23, 2023, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Sixth day of January, 2024



Secretary of State

Tracking Number: 3007199559CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 20531
Insp # 180940

NAME	PERMIT NUMBER	DATE OF INSPECTION
MANATEE PHARMACY SERVICES, INC	27278	07/17/2023
DOING BUSINESS AS		
MANATEE DISCOUNT PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
1802 59TH STREET WEST	941-209-1234	
CITY	**COUNTY**	**STATE/ZIP**
BRADENTON	MANATEE	FL/34209

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9 AM to 7 PM
Monday N	Monday Hours
Tuesday N	Tuesday Hours
Wednesday N	Wednesday Hours
Thursday N	Thursday Hours
Friday N	Friday Hours
Saturday Y	Saturday Hours 10 AM to 1 PM
Sunday N	Sunday Hours off

Registered Pharmacist / Intern / Tech

License # PS57604	Licensee Name HAMAD UDDIN NAWAZ
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FM4398930	

License Relations

Pharmacy Affiliate

KAZLOVA, YULIYA	License #
NAWAZ, AQSA	License #

RX DPT MGR/COR/POR

NAWAZ, HAMAD UDDIN	License # 57604

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.]	Yes
A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C]	Yes

Community Requirements General Section

Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	Yes

Insp # 180940

INV359 - Community Requirements

MANATEE PHARMACY SERVICES, INC

File # 20531

Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.].	Yes
Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.]	Yes
Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.]	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes

Additional Community Requirements

Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.]	Yes
Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]	Yes
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	Yes
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summerization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.] *Log kept in department. Last dated 5.1.2023.*	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	Yes
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.]	Yes
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11]	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)] *Found electronically.*	Yes
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	Yes
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]	Yes
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.] *Automated daily thru electronic software.*	Yes
Compounding records properly maintained. [64B16-28.140(4), F.A.C.] *Log found in the department.*	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.] *Abc invoices found in the department.*	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.]	Yes
Pharmacist has a written collaborative practice agreement. [465.1865, F.S.] *Pharmacist owns facility.*	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs. *UPS performs function and meds sealed in container with patient information and literature.*	Yes

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The originating pharmacy is identified with pharmacy name and address on the prescription container label.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

Inspection:with Pharmacist/owner.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

MILLER, GARY

Date:7/17/2023

Representative:

hamad nawaz

Date:7/17/2023

AC# 1129253

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/8/2022	PHR 27673	139655

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF THE LAWS AND RULES OF THE STATE OF FLORIDA

Expiration Date: FEBRUARY 28, 2023

MANATEE PHARMACY SERVICES, INC.
Manatee Discount Pharmacy
1201 59TH STREET WEST
BRADENTON, 34209

CLASSIFICATION(S):
Community Pharmacy

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, M.D., Ph.D.
State Surgeon General

DISPLAY AS REQUIRED BY LAW

December 30, 2023

Board Of Pharmacy
1802 59Th Street West
Bradenton, FL 34209

RE: License Certification for Manatee Pharmacy Services, Inc

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH27278
ORIGINAL CERTIFICATION:	12/10/2013
EXPIRATION DATE:	02/28/2025
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No
LICENSE GRANTED BY:	N/A
OTHER CERTIFICATIONS:	Community Pharmacy, Schedule Ii & Iii

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gwendolyn B. Freeman

Gwendolyn B. Freeman
Operations and Management Consultant Manager

Manatee Discount PHARMACY

January 13, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Reno, NV 89521
Phone: (775) 850-1440

CC: compliance@mdprx.com

RE: Ownership/Officers/Directors/Stock Information for NV

Manatee Pharmacy Services, Inc., is the sole owner of Manatee Discount Pharmacy.

Name: Manatee Pharmacy Services, Inc. (Ownership 100%)
D/B/A: Manatee Discount Pharmacy
FEIN Tax ID: 46-4131646
Address: 1802 59th Street West. Bradenton, FL 34209
State of Incorporation: Florida

Corporate Officer 1:

- Name: Hamad Uddin Nawaz
- Officer Title: CEO/President/Director/PIC
- Ownership: Owner 40%
- Home Address: [redacted]78th Street Circle East. Bradenton, FL 34209
- Business Address: 1802 59th Street West. Bradenton, FL 34209
- Home Phone: [redacted]
- Business Phone: 941-209-1234
- DOB: [redacted]

Corporate Officer 2:

- Name: Aqsa Nawaz-Chowdhry
- Officer Title: CFO/Vice President
- Ownership: Owner 30%
- Home Address: [redacted]Legends Parkway. Fort Wayne, IN 46835
- Business Address: 1802 59th Street West. Bradenton, FL 34209
- Home Phone: [redacted]
- Business Phone: 941-209-1234
- DOB: [redacted]

Corporate Officer 3:

- Name: Yuliya Kazlova
- Officer Title: Treasurer/Secretary
- Ownership: Owner 30%
- Home Address: [redacted]Rock Creek Circle. Ellenton, FL 34222
- Business Address: 1802 59th Street West. Bradenton, FL 34209
- Home Phone: [redacted]
- Business Phone: 941-209-1234
- DOB: [redacted]

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM4398930	01-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-03-2022

MANATEE PHARMACY SERVICES,INC
MANATEE DISCOUNT PHARMACY
1802 59TH ST W
BRADENTON, FL 34209

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM4398930	01-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-03-2022

MANATEE PHARMACY SERVICES,INC
MANATEE DISCOUNT PHARMACY
1802 59TH ST W
BRADENTON, FL 34209

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2018)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Manatee Pharmacy Services DBA Manatee Discount Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1802 59th Street West

City: Bradenton State: FL Zip: 34209

Mailing Address (if different from physical address): 1802 59th Street West

City: Bradenton State: FL Zip: 34209

Telephone: 941-209-1234 Website: https://www.mygnp.com/pharmacies/manatee-discount-pharmacy-bradenton-FL-34209

Licensing Company Email: compliance@mdprx.com

Section 2: Personal Information

First: Aqsa Middle: Last: Nawaz-Chowdhry

Alias(es, nicknames, name changes, etc.): Aqsa Nawaz

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted] Legends Pkwy

City: Fort Wayne State: IN Zip: 46835

Telephone: [redacted] Email: compliance@mdprx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Alabama at Birmingham		06/16-05/17	
Address	**City**	**State**	**Zip**
1720 University Blvd.	Birmingham	AL	35294
Diploma/Degree obtained, if any			
BS-Industrial Distribution			

School Name		From - To (MM/YY – MM/YY)	
University of Alabama at Birmingham		08/06-05/09	
Address	**City**	**State**	**Zip**
1720 University Blvd.	Birmingham	AL	35294
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Hoover High School		08/02-05/06	
Address	**City**	**State**	**Zip**
1000 Buccaneer Dr	Hoover	AL	35244
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19-07/24	[redacted] Legends Pkwy	Fort Wayne	IN	46835
04/17-05/19	[redacted] Bella Grove Circle Unit 409	Sarasota	FL	34243
02/14-04/17	[redacted] Deer Trail Road	Hoover	AL	35226
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Manatee Pharmacy Services DBA Manatee Discount Pharmacy			04/17-07/24
Business Address	**City**	**State**	**Zip**
1802 59th Street West	Bradenton	FL	34209
Phone	**Title**		
941-209-1234	Vice President		
Description of Duties			
Administrative work and marketing			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Aqsa Nawaz-Chaudhry
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/17/2024
Date

Please have this section completed in the presence of a Notary Public.

State of INDIANA, ss. County of ALLEN

I, Aqsa Nawaz-Chaudhry, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/17/2024
Date

Subscribed and Sworn to before me this 17 day of July, 2024

Karen Buuck
Notary Public Signature

NOTARY PUBLIC SEAL INDIANA

KAREN BUUCK, Notary Public
ALLEN County, State of Indiana
Commission Number NP0746944
My Commission Expires Feb 19, 2031

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Manatee Pharmacy Services DBA Manatee Discount Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1802 59th ST W

City: Bradenton State: FL Zip: 34209

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 9412091234 Website: https://www.mygnp.com/pharmacies/manatee-discount-pharmacy-bradenton-FL-34208/

Licensing Company Email: compliance@mdprx.com

Section 2: Personal Information

First: Yuliya Middle: Last: Kazlova

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]ock creek cir

City: ellenton State: fl Zip: 34222

Telephon[redacted] Email: compliance@mdprx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Minsk state linguistic university		09/01-07/2004	
Address	**City**	**State**	**Zip**
	Minsk	Belarus	
Diploma/Degree obtained, if any			
Bachelor			

School Name		From - To (MM/YY – MM/YY)	
High school #2		09/99-07-2001	
Address	**City**	**State**	**Zip**
	Oshmyany	Belarus	
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/10-current	[redacted] rock creek cir	ellenton	fl	34222
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Manatee Discount Pharmacy			01/2017-current
Business Address	**City**	**State**	**Zip**
1802 59th ST W	Bradenton	FL	34209
Phone	**Title**		
9412091234	Treasurer/ pharmacy techinician		
Description of Duties			
Customer Service, Prescription processing, inventory management. Financial duties			

Business Name			From - To (MM/YY – MM/YY)
Genoa Pharmacy			01/2014-01/2017
Business Address	**City**	**State**	**Zip**
379 6th ave w	bradenton	fl	34205
Phone	**Title**		
9417489409	Pharmacy Technician		
Description of Duties			
Customer Service, Prescription processing, inventory management.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yuliya Kazlova

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/17/2024

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of MANATEE

I, YULIYA KAZLOVA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7.18.24

Date

Subscribed and Sworn to before me this 18 day of JULY, 2024

Notary Public Signature

ANNETTE MOORE-RUSSELL
Notary Public, State of Florida
Commission# HH 404543
My comm. expires May. 30, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section I: Pharmacy/MDEG/Wholesaler/Dispensing Site Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Manatee Pharmacy Services, Inc (DBA Manatee Discount Pharmacy)
Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 27278
Physical Address: 1802 59TH STREET WEST
City: BRADENTON State: FL Zip: 34209
Mailing Address (if different from physical address): SAME
City: SAME State: SAME Zip: SAME
Telephone: 941-209-1234 Website: https://www.mygnp.com/pharmacies/manatee-discount-pharmacy-bradent
Licensing Company Email: COMPLIANCE@MDPRX.COM

Section II: Personal Information

First: HAMAD Middle: UDDIN Last: NAWAZ
Alias(es, nicknames, name changes, etc.): N/A
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X
Mailing Address: [redacted]78TH STREET CIRCLE EAST
City: BRADENTON State: FL Zip: 34208
Telephone: [redacted] Email: COMPLIANCE@MDPRX.COM
Are you a citizen of the United States? ☒ Yes ☐ No

Section III: Military Service Information

	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section IV: Family Support Requirement (NRS 622.200)

	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

School Name			From - To (MM/YY – MM/YY)
Auburn University Harrison School of Pharmacy			08/12 - 05/16
Address	City	State	Zip
2316 Walker Bldg	Auburn	AL	36849
Diploma/Degree obtained, if any			
PharmD			

School Name			From - To (MM/YY – MM/YY)
UAB			08/08 - 05/12
Address	City	State	Zip
1720 2nd Ave S.	Birmingham	AL	35294
Diploma/Degree obtained, if any			
Bachelor in Biology			

School Name			From - To (MM/YY – MM/YY)
Hoover High School			08/04 - 05/08
Address	City	State	Zip
1000 Buccaneer Dr.	Hoover	AL	35244
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18 - Current	[redacted] 78TH STREET CIRCLE EAST	BRADENTON	FL	34209
01/04 - 12/18	[redacted] Deer Trail Rd	Hoover	AL	35226
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 2: Beginning with the most current employment in your work history and explore any partnerships and business ventures with which you have been involved. Include all other clients, the activities, stockholder, partner, owner, or employee status, and the dates for the last 10 years.

Business Name		From - To (MM/YY – MM/YY)
MANATEE PHARMACY SERVICES, INC (DBA MANATEE DISCOUNT PHARMACY)		03/19 - PRESENT
Business Address	**City / State / Zip**	
1802 59TH STREET WEST	BRADENTON / FL / 34209	
Phone	**Title**	
941-209-1234	PRESIDENT/CEO/DIRECTOR/PIC	

Description of Duties

I AM ONE OF THE PRINCIPALS OF THIS PHARMACY AND ALSO SERVE AS THE PIC. RESPONSIBILITIES INCLUDE MANAGING ALL PHARMACY OPERATIONS FROM INTAKE, ASSEMBLY, DISPENSING, COUNSELING, ETC.

Business Name		From - To (MM/YY – MM/YY)
WALMART PHARMACY		05/18 - 03/19
Business Address	**City / State / Zip**	
8320 Lockwood Ridge Rd	SARASOTA / FL / 34243	
Phone	**Title**	
941-351-7060	STAFF PHARMACIST	

Description of Duties

AS A STAFF PHARMACIST, I RAN THE PHARMACY OPERATIONS ON DAYS I WAS SCHEDULED TO WORK. THIS INCLUDES ALL TASKS SUCH AS INTAKE, ASSEMBLY, DISPENSING, COUNSELING, ETC.

Business Name		From - To (MM/YY – MM/YY)
WALMART PHARMACY		08/16 - 05/18
Business Address	**City / State / Zip**	
750 Academy Dr.	~~BOSMER~~ Bessemer / AL / 35022	
Phone	**Title**	
205-424-5895	STAFF PHARMACIST	

Description of Duties

AS A STAFF PHARMACIST, I RAN THE PHARMACY OPERATIONS ON DAYS I WAS SCHEDULED TO WORK. THIS INCLUDES ALL TASKS SUCH AS INTAKE, ASSEMBLY, DISPENSING, COUNSELING, ETC.

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City / State / Zip**	
	/ /	
Phone	**Title**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City / State / Zip**	
	/ /	
Phone	**Title**	

Description of Duties

Continue on next page if additional space is needed.

1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HAMAD NAWAZ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-15-24

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Manatee

I, Hamad Uddin Nawaz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-16-24

Date

Subscribed and Sworn to before me this 16 day of January.

Notary Public Signature

Michelle Butler
Notary Public, State of Florida
My Commission Expires 06/02/2025
Commission No. HH 372993

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Manatee Pharmacy Services, Inc (DBA Manatee Discount Pharmacy)

Pharmacy/Wholesaler License # (if applicable): PH 27278

Physical Address: 1802 59TH STREET WEST

City: BRADENTON State: FL Zip: 34209

Mailing Address (if different from physical address): SAME

City: SAME State: SAME Zip: SAME

Telephone: 941-209-1234 Website: https://www.mygnp.com/pharmacies/manatee-discount-pharmacy-braden

Licensing Company Email: COMPLIANCE@MDPRX.COM

Section 2: Personal Information

First: HAMAD Middle: UDDIN Last: NAWAZ

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]78TH STREET CIRCLE EAST

City: BRADENTON State: FL Zip: 34209

Telephone: [redacted] Email: COMPLIANCE@MDPRX.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Auburn University Harrison School of Pharmacy		08/12-5/16	
Address	**City**	**State**	**Zip**
2316 Walker Bldg	Auburn	AL	36849
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
UAB		08/18-05/12	
Address	**City**	**State**	**Zip**
1720 2nd Ave S	Birmingham	AL	35294
Diploma/Degree obtained, if any			
Bachelor in Biology			

School Name		From - To (MM/YY – MM/YY)	
Hoover High School		08/04-05/08	
Address	**City**	**State**	**Zip**
1000 Buccaneer Dr	Hoover	AL	35244
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18 - Current	[redacted]78th Street Circle East	Bradenton	FL	34209
01/04 - 12/18	[redacted] Deer Trail Rd	Hoover	AL	35226
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Manatee Pharmacy Services, Inc (DBA Manatee Discount Pharmacy)			03/19-Present	
Business Address		**City**	**State**	**Zip**
1802 59th Street West		Bradenton	FL	34209
Phone	**Title**		**Number of Employed Hours**	
941-209-1234	President/CEO//Director/PIC		40 hours weekly	
Description of Duties				
I am one of the principals of this pharmacy and also serve as the PIC, responsibilties include managing all pharmacy operations from intake, assembly, dispensing, counseling, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Walmart Pharmacy			05/18 - 03/19	
Business Address		**City**	**State**	**Zip**
8320 Lockwood Ridge Rd		Sarasota	FL	34243
Phone	**Title**		**Number of Employed Hours**	
941-351-7060	Staff Pharmacsit		40 hours weekly	
Description of Duties				
As a staff pharmacsit, I ran the pharmacy operations on days I was scheduled to work. This includes all tasks such as intake, assembly, dispensing, counseling, etc				

Business Name			From - To (MM/YY – MM/YY)	
Walmart Pharmacy			06/16-05/18	
Business Address		**City**	**State**	**Zip**
750 Academy Dr		Bessemer	AL	35022
Phone	**Title**		**Number of Employed Hours**	
205-424-5895	Staff Pharmacist		40 hours weekly	
Description of Duties				
As a staff pharmacsit, I ran the pharmacy operations on days I was scheduled to work. This includes all tasks such as intake, assembly, dispensing, counseling, etc				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, HAMAD NAWAZ, **certify that as the designated representative for**

Manatee Pharmacy Services, Inc (DBA Manatee Discount Pharmacy),

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. YES I am at least 21 years of age;
3. YES I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. YES I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. YES I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. YES I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. YES I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

HAMAD NAWAZ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-15-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HAMAD NAWAZ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-15-24

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Manatee

I, Hamad Uddin Nawaz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-16-24

Date

Subscribed and Sworn to before me this 16 day of January.

Notary Public Signature

Michelle Butler
Notary Public, State of Florida
My Commission Expires 06/02/2025
Commission No. HH 372993

(Seal)

4YY

RECEIVED 2/26/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH:	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: shipping pharmacy	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FN0730425 ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Shipping services

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: NextRx Pharmacy

Physical Address: 2909 Falling Leaf Lane Ste A

City: Columbia State: MO Zip: 65201

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 573-545-5278 Toll Free # (NAC 639.708, NRS 639.23286): 866-860-6467

Fax: 573-545-5302 Contact Email: kierstyn@nextrx.com

Website: www.nextrx.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Kierstyn Gillooly

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): ~~n/a~~ 24258

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kierstyn Gillooly	NV Pharmacist Registration #: ~~n/a~~ 24258
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Pharma Group Select LLC

Mailing Address: [redacted]

City: Osage Beach State: MO Zip: 65065

Telephone: [redacted] Email: neal@nextrx.com

Contact Person Name: Neal Head

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

nevada

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for NextRx Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Neal R Head

Print Name of Authorized Person

Neal R. Head

Original signature of Authorized Person (copies or stamps not accepted)

02/18/2024

Date

Nevada

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Neal R Head hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for NextRx Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

x Neal Head
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 15 day of February, 20 24

Teresa M. Tice
Notary Public

TERESA M TICE
Notary Public - Notary Seal
STATE OF MISSOURI
Boone County
My Commission Expires 1/2/2026
Commission # 22182216

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Neal Head

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

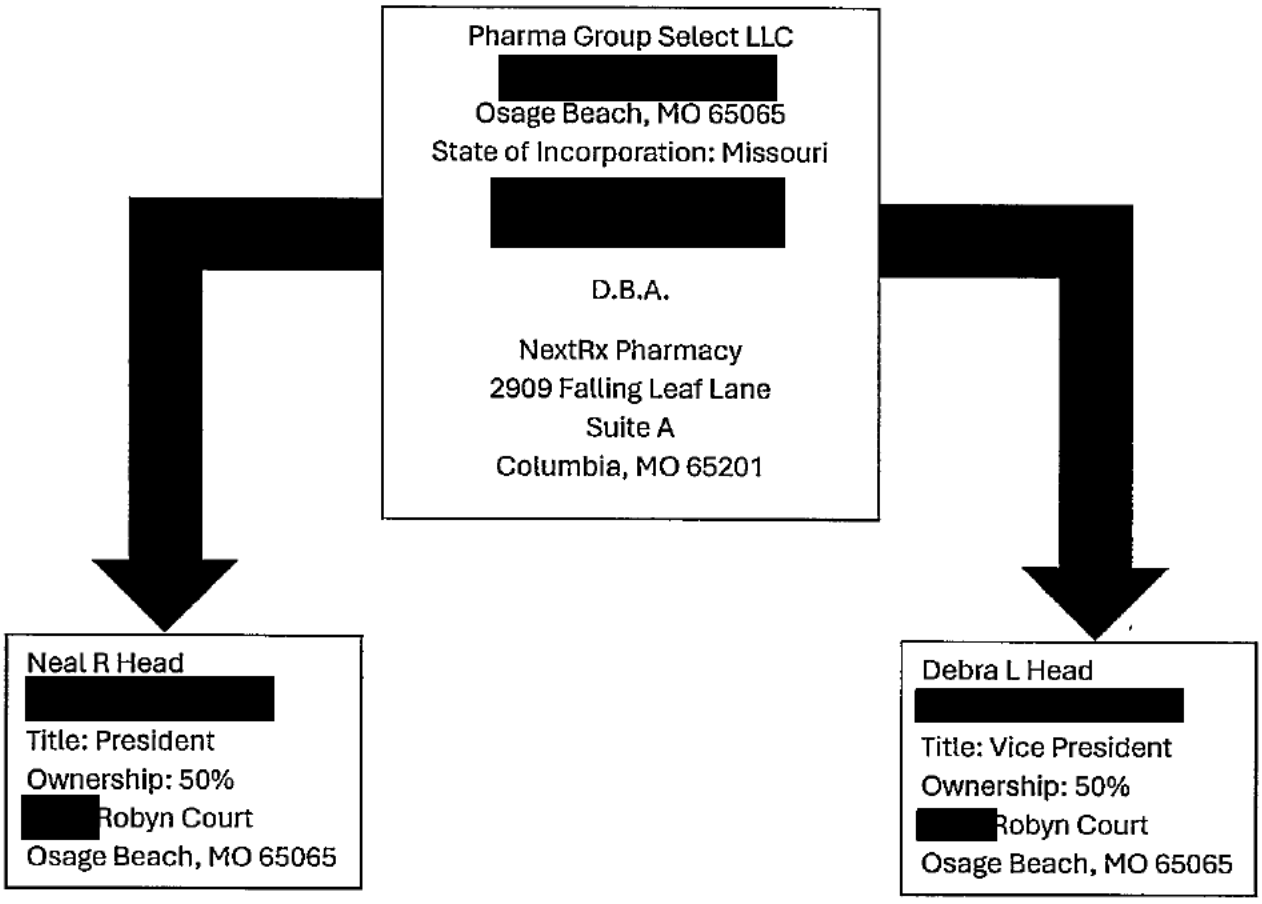
Neal Head

Original signature of Authorized Person (copies or stamps not accepted)

02/18/2024

Date

Board Use Only	Date Received: 2/26/24	Amount: $500-check 1371 ✓


Pharma Group Select LLC
[redacted]
Osage Beach, MO 65065
State of Incorporation: Missouri
[redacted]
D.B.A.
NextRx Pharmacy
2909 Falling Leaf Lane
Suite A
Columbia, MO 65201
Neal R Head
[redacted]
Title: President
Ownership: 50%
[redacted]Robyn Court
Osage Beach, MO 65065
Debra L Head
[redacted]
Title: Vice President
Ownership: 50%
[redacted]Robyn Court
Osage Beach, MO 65065

IN WITNESS WHEREOF, the parties hereto have hereunto signed this Operating Agreement on the day and year first above written.

Neal Head
NEAL HEAD, Member

Debra Head
DEBRA HEAD, Member

STATE OF MISSOURI)
)ss.
COUNTY OF Camden)

On this 15th day of March, 2021, before me personally appeared NEAL HEAD to me known to be the person described in and who executed the foregoing instrument and acknowledged that he executed the same as his free act and deed.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at my office in the county and state written above on the day and year first above written.

NOTARY PUBLIC NOTARY SEAL STATE OF MISSOURI

MICHELLE SCHOONOVER
My Commission Expires
August 8, 2022
Miller County
Commission #18961762

Michelle Schoonover
NOTARY PUBLIC

STATE OF MISSOURI)
)ss.
COUNTY OF Camden)

On this 15th day of March, 2021, before me personally appeared DEBRA HEAD, to me known to be the person described in and who executed the foregoing instrument and acknowledged that she executed the same as her free act and deed.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at my office in the county and state written above on the day and year first above written.

NOTARY PUBLIC NOTARY SEAL STATE OF MISSOURI

MICHELLE SCHOONOVER
My Commission Expires
August 8, 2022
Miller County
Commission #18961762

Michelle Schoonover
NOTARY PUBLIC

STATE OF MISSOURI

John R. Ashcroft
Secretary of State

CORPORATION DIVISION
CERTIFICATE OF GOOD STANDING

I, JOHN R. ASHCROFT, Secretary of State of the STATE OF MISSOURI, do hereby certify that the records in my office and in my care and custody reveal that

Pharma Group Select LLC
LC1765696

was created under the laws of this State on the 24th day of February, 2021, and is active, having fully complied with all requirements of this office.

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, this 29th day of January, 2024.

Secretary of State

Certification Number: CERT-01292024-0097

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler NextRx Pharmacy

Pharmacy/Wholesaler License # (if applicable) 2021033160

Physical Address 2909 Falling Leaf Lane Ste A

City Columbia State MO Zip 65201

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 573-545-5278 Website www.nextrx.com

Licensing Company Email ~~neal@nextrx.com~~ info@nextrx.com

Section 2: Personal Information

First Kierstyn Middle Thea Last Gillooly

Alias(es, nicknames, name changes, etc.) Fornoff

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] State Road O

City Fulton State MO Zip 65251

Telephone [redacted] Email kierstyn@nextrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Health Sciences and Pharmacy		08/09-05/15	
Address	**City**	**State**	**Zip**
1 Pharmacy Place	St. Louis	MO	63110
Diploma/Degree obtained, if any			
Doctor of Pharmacy (Pharm.D.)			

School Name		From - To (MM/YY – MM/YY)	
South Callaway High School		08/05-05/09	
Address	**City**	**State**	**Zip**
10135 State Highway C	Mokane	MO	65059
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/19-current	[redacted] State Road O	Fulton	MO	65251
09/15-09/19	[redacted] Basalt Lane	Fulton	MO	65251
05/15-09/15	[redacted] State Road O	Fulton	MO	65251
03/12-05/15	[redacted] Fyler Avenue	St. Louis	MO	63139

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
NextRx Pharmacy			11/23-current
Business Address	**City**	**State**	**Zip**
2909 Falling Leaf Lane Ste A	Columbia	MO	65201
Phone	**Title**	**Number of Employed Hours**	
573-545-5278	Pharmacist in Charge	48 hours per week	

Description of Duties
manage staff, purchasing, inventory, pricing, contracts, licenses, compliance with federal and state laws, fill prescriptions, DUR, counseling, contacting doctor's offices to resolve issues

Business Name			From - To (MM/YY – MM/YY)
CVS inside Target			12/22-11/23
Business Address	**City**	**State**	**Zip**
735 W Stadium Blvd	Jefferson City	MO	65109
Phone	**Title**	**Number of Employed Hours**	
573-893-1079	Pharmacist in Charge	32 hours per week	

Description of Duties
manage staff, purchasing, inventory, scheduling, compliance with federal and state laws, fill prescriptions, DUR, counseling

Business Name			From - To (MM/YY – MM/YY)
CVS inside Schnucks			09/22-12/22
Business Address	**City**	**State**	**Zip**
1801 Missouri Blvd	Jefferson City	MO	65109
Phone	**Title**	**Number of Employed Hours**	
573-635-8910	Pharmacist Trainer	40 hours per week	

Description of Duties
manage staff, train new pharmacist in charge how to manage of pharmacy

Business Name			From - To (MM/YY – MM/YY)
CVS			06/22-09/22
Business Address	**City**	**State**	**Zip**
500 N Bishop Ave	Rolla	MO	65401
Phone	**Title**	**Number of Employed Hours**	
573-308-4887	Pharmacist in Charge - interim	40 hours per week	

Description of Duties
manage staff, purchasing, inventory, scheduling, compliance with federal and state laws, fill prescriptions, DUR, counseling, evaluate and integrate policies/procedures to clean up and maintain pharmacy once cleaned up

Business Name			From - To (MM/YY – MM/YY)
CVS			01/21-06/22
Business Address	**City**	**State**	**Zip**
600 Court St	Fulton	MO	65251
Phone	**Title**	**Number of Employed Hours**	
573-642-6892	Staff Pharmacist	32 hours per week	

Description of Duties
fill prescriptions, purchasing, DUR, counseling, assisting PIC with duties in their absence

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Hy-Vee			08/16-12/20	
Business Address		City	State	Zip
3721 W Truman Blvd		Jefferson City	MO	65109
Phone	Title		Number of Employed Hours	
573-634-2628	Staff Pharmacist		40 hours per week	
Description of Duties				
fill prescriptions, purchasing, DUR, counseling, assissting PIC with duties in their absence				

Business Name			From - To (MM/YY – MM/YY)	
Hy-Vee			07/15-07/16	
Business Address		City	State	Zip
3100 W Broadway		Columbia	MO	65203
Phone	Title		Number of Employed Hours	
573-447-2144	Staff Pharmacist		40 hours per week	
Description of Duties				
fill prescriptions, purchasing, DUR, counseling, assissting PIC with duties in their absence				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Kierstyn Gillooly, **certify that as the designated representative for**

NextRx Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KG I am at least 21 years of age;
3. KG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kierstyn Gillooly
Print Name (First, Last)

Kierstyn Gillooly
Original Signature (electronic, copies or stamps not accepted)

2/18/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kierstyn Gillooly

Print Name (First, Last)

Kierstyn Gillooly

Original Signature (electronic, copies or stamps not accepted)

02/18/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of Boone

I, Kierstyn Gillooly, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Kierstyn Gillooly

Original Signature

2/21/2024

Date

Subscribed and Sworn to before me this 21st day of February.

Notary Public Signature

TAYLOR KNIPP
Notary Public - Notary Seal
STATE OF MISSOURI
Callaway County
My Commission Expires 12/13/2025
Commission # 17733529

(Seal)

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

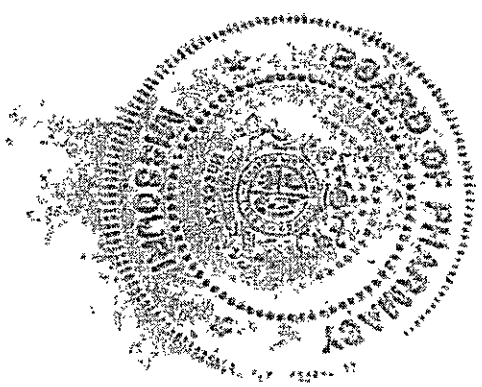
Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109-0625
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

This is to certify that the records of the Missouri Division of Professional Registration indicate the following information regarding Gillooly, Kierstyn T.

LICENSE TYPE:	Pharmacist
LICENSE NUMBER:	2015026245
ADDRESS:	Fulton, MO 65251
DATE ISSUED:	7/27/2015
STATUS:	Active
EXPIRATION DATE:	10/31/2024
DISCIPLINARY ACTION:	None



Missouri Board of Pharmacy

2/20/24

Date

This is the only form that will be used by the Missouri Board of Pharmacy for the purpose of license verification.

STATE OF MISSOURI
BOARD OF PHARMACY

COPY

MAILING ADDRESS
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985
(573) 526-3464 FAX
PHARMACY@PR.MO.GOV

PHARMACY INSPECTION REPORT

NAME/ADDRESS OF PHARMACY	LICENSE NUMBER	CLASS	INSPECTION DATE
NextRx 2909 Falling Leaf Ln. Columbia MO 65201	2021033160	A	12/20/2023

PHARMACIST-IN-CHARGE	PIC LICENSE NO
Kierstyn Gillooly	2015026245

LAST CONTROLLED SUBSTANCES INVENTORY	ADMINISTRATIONS
9/21/2023	☐ Yes ☑ No

PHONE	Fax	Email	STERILE COMPOUNDING
5735455278	5735455302	kierstyn@nextrx.com	☐ Yes ☑ No

Inspection Type: Routine ***Inspection Result:*** Compliance Notice ***Inspector:*** Scott Spencer

Start Time: 11:30 AM ***End Time:*** 1:54 PM ***Acknowledged By:*** Kierstyn Gillooly

This report is based solely on the inspector's observations of a random sampling of the pharmacy's activities. Licensees should review Missouri law to ensure compliance

LICENSES/REGISTRATION

	Y	N	N/A
Pharmacy permit is current and posted [20 CSR 2220-2.020(5)]	☑	☐	☐
Permit has correct class(es) [20 CSR 2220-2.020(10)]	☑	☐	☐
All licenses/registrations current and posted [§ 338.013.3]	☑	☐	☐
Technician list maintained [20 CSR 2220-2.090(2)(BB)]	☐	☐	☑
BOP offsite storage notifications submitted [20 CSR 2220-2.010(1)(I), (J)]	☐	☐	☑
BOP remodel notifications submitted [20 CSR 2220-2.020(4)]	☐	☐	☑

Observations

PHARMACY OPERATIONS

	Y	N	N/A
Pharmacy is clean/sanitary [20 CSR 2220-2.010(1)(F)]	☑	☐	☐
Proper sanitation used in dispensing process [20 CSR 2220-2.010(1)(F)]	☑	☐	☐
Adequate security maintained to deter drug theft [20 CSR 2220-2.010(H)]	☑	☐	☐
Hot/cold water sewage disposal available and functioning [20 CSR 2220-2.090(2)(V)]	☐	☐	☑
Required drug reference(s) available [20 CSR 2220-2.010(2)(C)]	☐	☐	☑
Dispensing equipment clean/working condition [20 CSR 2220-2.010(2)(C)]	☑	☐	☐
Vacuum-tube delivery system working properly [20 CSR 2220-2.800]	☐	☐	☑
Automated dispensing/storage system meets requirements [20 CSR 2220-2.900]	☐	☐	☑
Automated filling system meets requirements [20 CSR 2220-2.950]	☐	☐	☑

Observations

PHARMACIST SUPERVISION

	Y	N	N/A
Pharmacist on duty or signs posted [20 CSR 2220-2.010(1)(A)]	☑	☐	☐
Technicians supervised, work verified by a pharmacist [20 CSR 2220-2.700(1); 2.010 (1)(B)]	☑	☐	☐

Observations

POLICIES AND PROCEDURES

	Y	N	N/A
Policies and procedures available and followed	☑	☐	☐
Policies and procedures cover required topics	☐	☐	☑

Observations

DRUG INVENTORY/STORAGE

	Y	N	N/A
Drug storage temperature in required range [20 CSR 2220-2.010(2)(G)]	☑	☐	☐
Thermometer/temp measuring device present and functioning [20 CSR 2220-2.010(2)(F)]	☐	☑	☐
Drugs/devices properly separated from food/beverages [20 CSR 2220-2.010(1)(G)]	☑	☐	☐
Expired/misbranded/adulterated drugs separate from active inventory [20 CSR 2220-2.010(6)]	☑	☐	☐
Return to stock prescriptions in original container/properly labeled [20 CSR 2220-3.040(3)]	☑	☐	☐

Observations

-Failure to record temperatures in all drug storage areas (No ambient temperature record for 11/24/2023).

RECEIPT/DISTRIBUTION OF DRUGS

	Y	N	N/A
Records maintained for receipt of legend drugs [20 CSR 2220-2.010(5)]	☑	☐	☐
Receiving legend drugs from licensed entities [§ 338.315]	☑	☐	☐
Records maintained for distribution of legend drugs [20 CSR 2220-2.010(5)]	☑	☐	☐

Observations

REPACKAGING/PREPACKAGING

	Y	N	N/A
Appropriate containers/packaging used [20 CSR 2220-2.130(1)(B)]	☑	☐	☐
Label contains required elements [20 CSR 2220-2.130(1)(D)]	☑	☐	☐
Expiration date complies with 20 CSR 2220-2.130(1)(D)	☑	☐	☐

Observations

DISPENSING RECORDS

	Y	N	N/A
Prescription files or images properly maintained [20 CSR 2220-2.010(4), 2.083]	☑	☐	☐
Manual prescription records comply with 20 CSR 2220-2.017	☐	☐	☑
Electronic prescription records comply with 20 CSR 2220-2.080	☑	☐	☐

Observations

DISPENSING/LABELING

	Y	N	N/A
Sampled prescriptions in required two-line format [§ 338.056]	☐	☐	☑
Sampled prescriptions contain all required information	☑	☐	☐
Sampled prescriptions dispensed as prescribed	☑	☐	☐
Sampled prescriptions comply with other applicable dispensing laws	☑	☐	☐
Generic substitutions comply with 338.056	☑	☐	☐
Prescription labels contain required information [§ 338.059]	☑	☐	☐
Child resistant packaging present [16 CFR 1700.14]	☑	☐	☐
Return to stock items properly reversed in computer system [20 CSR 2220-3.040(3)]	☑	☐	☐
Prescription transfers properly documented [20 CSR 2220-2.120(1)(a)]	☑	☐	☐
Verbal offer to counsel made to each patient [20 CSR 2220-2.190(1)]	☑	☐	☐
Written offer to counsel provided when required [20 CSR 2220-2.190(1)]	☐	☐	☑
Automated Filling System properly checked by pharmacist [20 CSR 2220-2.950(4)]	☐	☐	☑

Observations

LONG-TERM CARE DISPENSING

	Y	N	N/A
Packaging complies with 20 CSR 2220-2.140	☐	☐	☑
Sampled labels complete [20 CSR 2220-2.140(2)(B)]	☐	☐	☑
Proper sanitation used when packaging [20 CSR 2220-2.010(1)(F)]	☐	☐	☑
Proper return and reuse of medication [20 CSR 2220-3.030(1)(2)]	☐	☐	☑
Proper label changes for previously dispensed prescriptions [20 CSR 2220-2.140(2)(B)]	☐	☐	☑
Proper dispensing records maintained [20 CSR 2220-2.080; 20 CSR 2220-2.010(2)]	☐	☐	☑

Observations

MULTI-MED DISPENSING

	Y	N	N/A
Packaging and containers comply with 20 CSR 2220-2.145(2)(C), (D)	☐	☐	☑
Med paks properly labeled [20 CSR 2220-2.145(2)]	☐	☐	☑
Proper sanitation used when packaging [20 CSR 2220-2.010(1)(F)]	☐	☐	☑
Return/reuse complies with 20 CSR 2220-2.145(2)(H)	☐	☐	☑
Proper dispensing records maintained [20 CSR 2220-2.145(2)(F); 20 CSR 2220-2.080; 20 CSR 2220-2.010(2)]	☐	☐	☑

Observations

CONTROLLED SUBSTANCES

	Y	N	N/A
BNDD/DEA registrations current/active [§ 195.030.2; 21 CFR 1301.11]	☑	☐	☐
Sampled prescriptions comply with CS dispensing laws/rules	☑	☐	☐
CS prescriptions manually signed or valid electronic prescription [21 CFR § 1306.8]	☑	☐	☐
Medical reason for dispensing more than a 30-day supply of a C-II documented [§ 195.080.2]	☐	☐	☑
CS prescription quantity limits and partial fill requirements followed [195.080, 19 CSR 30-1.064]	☑	☐	☐
C-II drugs under lock/secure cabinet (19 CSR 30-1.034]	☑	☐	☐
C-III to IV dispersed in inventory or under lock/secure cabinet [19 CSR 30-1.034(1)]	☑	☐	☐
C-III to C-V invoices dated when received [19 CSR 30-1.048(4)]	☑	☐	☐
Loss reports properly filed [19 CSR 30-1.034(2)(B); 21 CFR 1301.76(b)]	☐	☐	☑

Observations

CONTROLLED SUBSTANCES INVENTORY

	Y	N	N/A
CS inventory available and taken annually and when required [19 CSR 30-1.042]	☐	☑	☐
CS inventory contains date and time taken [19 CSR 30-1.042(1)(D)]	☑	☐	☐
CS inventory includes C-V pseudoephedrine products [19 CSR 30-1.042]	☑	☐	☐
Pharmacist-in-charge change inventory taken [20 CSR 2220-2.090(2)(T)]	☑	☐	☐

Observations

-CS inventory not taken within one year of previous inventory (11/1/2021 to 9/21/2023, pharmacy unable to produce 2022 inventory during inspection)(See Compliance Notice).

C-II Ordering

	Y	N	N/A
Sampled CSOS or 222 forms, accessible, executed and complete [21 CFR § 1305.13, .22]	☑	☐	☐
CSOS usernames/passwords not shared [21 CFR §1305.21]	☐	☐	☑

Observations

OTC/PSEUDOEPHEDRINE SALES

	Y	N	N/A
Schedule V OTC PSE products behind counter or under lock [19 CSR 30-1.034]	☑	☐	☐
Combat Meth Act self-certification current [21 CFR 1306.8]	☑	☐	☐
Pseudoephedrine sales properly entered into database and accessible [19 CSR 30-1.074]	☑	☐	☐

Observations

ADMINISTRATION BY PROTOCOL

	Y	N	N/A
Protocol complete, current, signed/dated, and followed [20 CSR 2220-6.050(5)(B)]	☐	☐	☑
Administration records properly maintained [20 CSR 2220-6.050(6)]	☐	☐	☑
Vaccines are authorized by and age limits followed [§338.010]	☐	☐	☑

Observations

ADMINISTRATION BY PRESCRIPTION ORDER

	Y	N	N/A
Prescription requirements met [20 CSR 2220-6.040(5)]	☐	☐	☑
Administration records properly maintained [20 CSR 2220-6.040(6)]	☐	☐	☑

Observations

NON-STERILE COMPOUNDING

	Y	N	N/A
Compounding equipment functioning/maintained [20 CSR 2220-2.400(5)©]	☐	☐	☑
Active/therapeutic ingredients on prescription container [20 CSR 2220-2.400(7)(F)]	☐	☐	☑
Compound log accurately maintained [20 CSR 2220-2.400(7)]	☐	☐	☑
Other compounding records properly maintained [20 CSR 2220-2.400(7)]	☐	☐	☑
Bulk active ingredients meet compendial standards or certificate of analysis maintained [20 CSR 2220-2.400(8)(A)2]	☐	☐	☑
Return to stock items handled as batched with lot # and BUD on container label and documented in compound log [20 CSR 2220-2.400(7)(A), (D)]	☐	☐	☑
Batch/bulk compounds stored and labeled with lot # and BUD [20 CSR 2220-2.400(7)(A)6.]	☐	☐	☑
Adverse effects/complaints documented and investigated [20 CSR 2220-2.400(8)(B)]	☐	☐	☑
Recalls and prescriber/patient notifications conducted when required [20 CSR 2220-2.400(8)(C)]	☐	☐	☑

Observations

Additional Observations:

Additional Comments:

STATE OF MISSOURI
DIVISION OF PROFESSIONAL REGISTRATION

COMPLIANCE NOTICE
1901748

FOR OFFICE USE ONLY	
EXECUTIVE DIRECTOR	LICENSING TECHNICIAN

RETURN TO:
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985 (573) 526-3464 FAX
PHARMACY@PR.MO.GOV

DELIVERY ADDRESS:
MISSOURI BOARD OF PHARMACY
3605 MISSOURI BLVD
JEFFERSON CITY, MO 65109

3255

NAME OF PHARMACY OR DRUG DISTRIBUTOR
NextRx
2909 Falling Leaf Ln.
Columbia MO 65201 Boone

LICENSE NUMBER	CLASS	INSPECTOR	Territory	INSPECTION DATE
2021033160	A	Scott Spencer	7	12/20/2023

PHARMACIST OR MANAGER-IN-CHARGE	PIC/MIC LICENSE NO
Kierstyn Gillooly	2015026245

NOTICE IS HEREBY GIVEN THAT YOU ARE NOT COMPLYING WITH THE FOLLOWING LAWS AND/OR RULES.

RESPONSE TO COMPLIANCE NOTICE
EXPLAIN, IN THE SPACE PROVIDED BELOW, HOW THE NON-COMPLIANT CONDITION(S) WAS/WERE CORRECTED.
THE PERSON NAME ON THE COMPLIANCE NOTICE AS PHARMACIST-IN-CHARGE MUST SIGN THIS RESPONSE.
ATTACH ADDITIONAL PAGES AS NEEDED

1: 19 CSR 30-1.042(3) EXPLANATION OF VIOLATION -CS inventory not taken within one year of previous inventory (11/1/2021 to 9/21/2023, pharmacy unable to produce 2022 inventory during inspection).	1: We were able to locate the 2022 inventory in another file for 2022 controls. The inventory will be attached.
2: EXPLANATION OF VIOLATION	2:
3: EXPLANATION OF VIOLATION	3:

Notice is hereby given that a written response to this notice must be submitted to the Board of Pharmacy office on or before **12/30/2023**
The laws and/or rules cited above have been explained, and this notice has been provided to:
Kierstyn Gillooly

The failure to provide a written response may cause disciplinary action to be taken against your license.

PIC/MIC SIGNATURE: Kierstyn Gillooly

STATE OF MISSOURI
DIVISION OF PROFESSIONAL REGISTRATION

COMPLIANCE NOTICE
1901748

FOR OFFICE USE ONLY	
EXECUTIVE DIRECTOR	LICENSING TECHNICIAN

RETURN TO:
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985 (573) 526-3464 FAX
PHARMACY@PR.MO.GOV

DELIVERY ADDRESS:
MISSOURI BOARD OF PHARMACY
3605 MISSOURI BLVD
JEFFERSON CITY, MO 65109

3256

NAME OF PHARMACY OR DRUG DISTRIBUTOR
NextRx
2909 Falling Leaf Ln.
Columbia MO 65201 Boone

LICENSE NUMBER	CLASS	INSPECTOR	Territory	INSPECTION DATE
2021033160	A	Scott Spencer	7	12/20/2023

PHARMACIST OR MANAGER-IN-CHARGE	PIC/MIC LICENSE NO
Kierstyn Gillooly	2015026245

NOTICE IS HEREBY GIVEN THAT YOU ARE NOT COMPLYING WITH THE FOLLOWING LAWS AND/OR RULES.

RESPONSE TO COMPLIANCE NOTICE
EXPLAIN, IN THE SPACE PROVIDED BELOW, HOW THE NON-COMPLIANT CONDITION(S) WAS/WERE CORRECTED.
THE PERSON NAME ON THE COMPLIANCE NOTICE AS PHARMACIST-IN-CHARGE MUST SIGN THIS RESPONSE.
ATTACH ADDITIONAL PAGES AS NEEDED

4: EXPLANATION OF VIOLATION	4:
5: EXPLANATION OF VIOLATION	5:
6: EXPLANATION OF VIOLATION	6:

Notice is hereby given that a written response to this notice must be submitted to the Board of Pharmacy office on or before **12/30/2023**
The laws and/or rules cited above have been explained, and this notice has been provided to:
Kierstyn Gillooly

The failure to provide a written response may cause disciplinary action to be taken against your license.

PIC/MIC SIGNATURE: Kierstyn Gillooly

STATE OF MISSOURI
DIVISION OF PROFESSIONAL REGISTRATION

COMPLIANCE NOTICE
1901748

FOR OFFICE USE ONLY	
EXECUTIVE DIRECTOR	LICENSING TECHNICIAN

RETURN TO:
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985 (573) 526-3464 FAX
PHARMACY@PR.MO.GOV

DELIVERY ADDRESS:
MISSOURI BOARD OF PHARMACY
3605 MISSOURI BLVD
JEFFERSON CITY, MO 65109

3257

NAME OF PHARMACY OR DRUG DISTRIBUTOR
NextRx
2909 Falling Leaf Ln.
Columbia MO 65201 Boone

LICENSE NUMBER	CLASS	INSPECTOR	Territory	INSPECTION DATE
2021033160	A	Scott Spencer	7	12/20/2023

PHARMACIST OR MANAGER-IN-CHARGE: Kierstyn Gillooly
PIC/MIC LICENSE NO: 2015026245

NOTICE IS HEREBY GIVEN THAT YOU ARE NOT COMPLYING WITH THE FOLLOWING LAWS AND/OR RULES.

RESPONSE TO COMPLIANCE NOTICE
EXPLAIN, IN THE SPACE PROVIDED BELOW, HOW THE NON-COMPLIANT CONDITION(S) WAS/WERE CORRECTED.
THE PERSON NAME ON THE COMPLIANCE NOTICE AS PHARMACIST-IN-CHARGE MUST SIGN THIS RESPONSE.
ATTACH ADDITIONAL PAGES AS NEEDED

7: EXPLANATION OF VIOLATION	7:
8: EXPLANATION OF VIOLATION	8:
9: EXPLANATION OF VIOLATION	9:

Notice is hereby given that a written response to this notice must be submitted to the Board of Pharmacy office on or before **12/30/2023**
The laws and/or rules cited above have been explained, and this notice has been provided to:
Kierstyn Gillooly

The failure to provide a written response may cause disciplinary action to be taken against your license.

PIC/MIC SIGNATURE: Kierstyn Gillooly

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Pharmacy

Class A, C

VALID THROUGH OCTOBER 31, 2025
ORIGINAL CERTIFICATE/LICENSE NO. 2021033160
Kierstyn T Gillooly - 2015026245

PHARMA GROUP SELECT LLC -
NEXTRX
KIERSTYN GILLOOLY, PIC
2909 FALLING LEAF LN STE A
COLUMBIA, MO 65201
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

3258

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109-0625
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

This is to certify that the records of the Missouri Division of Professional Registration indicate the following information regarding Pharma Group Select LLC.

LICENSE TYPE:	Pharmacy
LICENSE NUMBER:	2021033160
ADDRESS:	Kierstyn Gillooly, PIC 2909 Falling Leaf Ln Ste A Columbia, MO 65201
DATE ISSUED:	8/17/2021
STATUS:	Active
EXPIRATION DATE:	10/31/2025
DISCIPLINARY ACTION:	None

Missouri Board of Pharmacy

02/06/2024
Date

This is the only form that will be used by the Missouri Board of Pharmacy for the purpose of license verification.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site NextRx Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 2021033160

Physical Address 2909 Falling Leaf Lane Ste A

City Columbia State MO Zip 65201

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 573-545-5278 Website www.nextrx.com

Licensing Company Email info@nextrx.com

Section 2: Personal Information

First Neal Middle Richard Last Head

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Robyn Court

City Osage Beach State MO Zip 65065

Telephone [redacted] Email neal@nextrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Missouri State University		08/82-05/83	
Address	**City**	**State**	**Zip**
901 S National Ave	Springfield	MO	65897
Diploma/Degree obtained, if any			
Master's in Secondary School Administration			

School Name		From - To (MM/YY – MM/YY)	
Truman State University		08/79-05/80	
Address	**City**	**State**	**Zip**
100 E Normal Ave	Kirksville	MO	63501
Diploma/Degree obtained, if any			
B.S. Physical Education			

School Name		From - To (MM/YY – MM/YY)	
Missouri Western State University		06/80-07/80	
Address	**City**	**State**	**Zip**
4525 Downs Dr	St. Joseph	MO	64507
Diploma/Degree obtained, if any			
n/a			

School Name		From - To (MM/YY – MM/YY)	
University of Central Missouri		08/78-05/79	
Address	**City**	**State**	**Zip**
116 W South St	Warrensburg	MO	64093
Diploma/Degree obtained, if any			
n/a			

School Name		From - To (MM/YY – MM/YY	
Moberly Area Community College		08/76-05/78	
Address	**City**	**State**	**Zip**
101 College Ave	Moberly	MO	65270
Diploma/Degree obtained, if any			
Associate of Arts			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/12-current	[redacted] Robyn Court	Osage Beach	MO	65065
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Pharma Group Select LLC DBA NextRx Pharmacy			02/21-current	
Business Address		**City**	**State**	**Zip**
2909 Falling Leaf Lane		Columbia	MO	65201
Phone	**Title**			
573-545-5278	President			
Description of Duties				
oversee the operations of the pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Pharma Group Alliance			05/13-01/21	
Business Address		**City**	**State**	**Zip**
[redacted]Robyn Ct		Osage Beach	MO	65065
Phone	**Title**			
[redacted]	President			
Description of Duties				
oversee the operations of multiple pharmacies				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Neal Head

Print Name (First, Last)

Neal Head

Original Signature (electronic, copies or stamps not accepted)

02/14/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of Boone

I, Neal Head, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Neal Head

Original Signature

2-15-2024

Date

Subscribed and Sworn to before me this 15th day of Feb 2024

Teresa M. Tice

Notary Public Signature

TERESA M TICE
Notary Public - Notary Seal
STATE OF MISSOURI
Boone County
My Commission Expires 1/2/2026
Commission # 22182246 (Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site NextRx Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 2021033160

Physical Address 2909 Falling Leaf Lane Ste A

City Columbia State MO Zip 65201

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 573-545-5278 Website www.nextrx.com

Licensing Company Email ~~neal@nextrx.com~~ info@nextrx.com

Section 2: Personal Information

First Debra Middle Lynn Last Head

Alias(es, nicknames, name changes, etc.) Stith

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Robyn Court

City Osage Beach State MO Zip 65065

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Truman State University		06/79-12/80	
Address	**City**	**State**	**Zip**
100 East Normal Ave	Kirksville	MO	63501
Diploma/Degree obtained, if any			
B.S. in Elementary Education			
School Name		**From - To (MM/YY – MM/YY)**	
Moberly Area Community College		08/77-05/79	
Address	**City**	**State**	**Zip**
101 College Ave	Moberly	MO	65270
Diploma/Degree obtained, if any			
Associate of Arts			
School Name		**From - To (MM/YY – MM/YY)**	
Livingston County RIV		08/73-05/77	
Address	**City**	**State**	**Zip**
n/a (no longer exists)	Wheeling	MO	64688
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/12-current	[redacted] Robyn Court	Osage Beach	MO	65065
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
retired teacher			05/13-current
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Debra Head

Print Name (First, Last)

Debra Head

Original Signature (electronic, copies or stamps not accepted)

02/14/2024

Date

Please have this section completed in the presence of a Notary Public.

State of (Debra Head) Missouri, ss. County of Miller

I, Debra Head, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Debra Head

Original Signature

2/20/2024

Date

Subscribed and Sworn to before me this 20th day of February

G M McDaniel

Notary Public Signature

G M MCDANIEL
NOTARY PUBLIC - NOTARY SEAL
STATE OF MISSOURI
MY COMMISSION EXPIRES NOVEMBER 8, 2025
MILLER COUNTY
COMMISSION #17981001

(Seal)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FN0730425	10-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	08-23-2021

NEXTRX PHARMACY
2909 FALLING LEAF LN STE A
COLUMBIA, MO 65201-3566

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
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Form DEA-223 (9/2016)

DEA 598
Granted: Oct 02 2023

ID# 220290171
Expires: Oct 31 2024

Self-Certification of Compliance

is hereby granted to

NEXTRX PHARMACY
2909 FALLING LEAF LN STE A
COLUMBIA, MO 652013566

The above referenced entity self-certifies that it is in compliance with all provisions related to the sale of ephedrine, pseudoephedrine, or phenylpropanolamine as required by the

COMBAT METHAMPHETAMINE EPIDEMIC ACT REQUIREMENTS

Self-Certified by

ERICA CRANE

The certifier affirms that he/she understands and agrees to comply with all the requirements specified in the Title 21 United States Code, Section 830. Fraudulent statements are subject to 18 USC 1001 penalties.

BUSINESS LICENSE CERTIFICATE

City of Columbia, MO
701 E. Broadway
Columbia, MO 65201
573-874-7378 or 573-874-7549

The Licensee named herein having paid to the City of Columbia the required fee, license is hereby granted to said Licensee to transact the business herein set forth for the period stated in conformity with the provisions of the Ordinances of this City.

Business Name: NEXT RX

License Number: BL017589
Issued Date: 11/16/2023
Expiration Date: 06/30/2024

Business Location: 2909 FALLING LEAF LN STE A
Owner: PHARMA GROUP SELECT LLC
Mailing Address:
PHARMA GROUP SELECT
2909 FALLING LEAF LN STE A
COLUMBIA, MO 65201

Classification: General Business License

License Official

Post license in a conspicuous place in room where business described is conducted.

4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH PH03768	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FP6777215 ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: PharmaCord

Physical Address: 11001 Bluegrass Parkway, Suite 200

City: Louisville State: KY Zip: 40299

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 502-805-3530 Toll Free # (NAC 639.708, NRS 639.23286): 866-743-0732

Fax: 502-805-3535 Contact Email: rx@pharmacord.com

Website: www.pharrnacord.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Chad Forinash

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 17753

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Chad Forinash	NV Pharmacist Registration #: 17753
Name: Kelly Johnson	NV Pharmacist Registration #: 23307
Name: Romina Perez Garces	NV Pharmacist Registration #: 23343
Name: Leslie Miller	NV Pharmacist Registration #: 23378
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): PC Acquisition Holdings I Inc. (23% owner) & Phantom Purchaser, Inc. (77% owner)

Corporation/Organization Name: PharmaCord, LLC

Mailing Address: 150 Hilton Dr

City: Jeffersonville State: Indiana Zip: 47130

Telephone: 502-805-3400 Email: rx@pharmacord.com

Contact Person Name: Cindy Padgett

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pres, Sec, Treas, & Managing Dir (title) for PharmaCord (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Nitin Sahney

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6-18-24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Nitin Sahney hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pres, Sec, Treas, & Managing Dir (title) for PharmaCord (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18 day of June, 20 21

Notary Public

SUZANNAH RHEA CLARK
Notary Public
Commonwealth of Kentucky
Commission Number KYNP52598
My Commission Expires Jul 12, 2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nitin Sahney

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6-18-24

Date

Board Use Only	Date Received: 6/24/24	Amount: $500-cc

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PHARMACORD LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF JUNE, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PHARMACORD LLC" WAS FORMED ON THE THIRTY-FIRST DAY OF OCTOBER, A.D. 2016.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



Jeffrey W. Bullock, Secretary of State

6206202 8300

SR# 20242833271

Authentication: 203676759

Date: 06-11-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Commonwealth of Kentucky
Michael G. Adams, Secretary of State

Michael G. Adams
Secretary of State
P. O. Box 718
Frankfort, KY 40602-0718
(502) 564-3490
http://www.sos.ky.gov

Certificate of Existence

Authentication number: 313071
Visit https://web.sos.ky.gov/ftshow/certvalidate.aspx to authenticate this certificate.

I, Michael G. Adams, Secretary of State of the Commonwealth of Kentucky, do hereby certify that according to the records in the Office of the Secretary of State,

PHARMACORD LLC

, a limited liability company authorized under the laws of the state of Delaware, is authorized to transact business in the Commonwealth of Kentucky, and received the authority to transact business in Kentucky on January 13, 2017.

I further certify that all fees and penalties owed to the Secretary of State have been paid; that an application for certificate of withdrawal has not been filed; and that the most recent annual report required by KRS 14A.6-010 has been delivered to the Secretary of State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my Official Seal at Frankfort, Kentucky, this 11th day of June, 2024, in the 233rd year of the Commonwealth.

Michael G. Adams
Secretary of State
Commonwealth of Kentucky
313071/0973219

Kentucky Board of Pharmacy
125 Holmes St.
Frankfort, KY 40601

Inspection Report

Pharmacy

Name: *PHARMACORD* **Permit No.:** *P07840*

Address: *11001 BLUEGRASS PARKWAY ste 200, LOUISVILLE, KY 40299*

Phone: *(502) 805-3530* **Fax:** *(502) 805-3535* **Email:** *rx@pharmacord.com*

Current:

Inspection

Date: *08/25/2022* **Time In:** *11:42 AM* **Time Out:** *1:10 PM*

Type: *Routine*

Notes: *None*

Pharmacist and Interns

KIMBERLY FITZGERALD ECKERLE
License: *009372* Status: *Active* PIC: *No*

Raven Luster
License: *PT00352804* Status: *Active* PIC: *No*

JERI KORBY
License: *PT00036695* Status: *Active* PIC: *No*

Brittany N Druin
License: *PT00364861* Status: *Active* PIC: *No*

LORI TOMPKINS FALL
License: *010339* Status: *Active* PIC: *No*

Bridget L Goldsmith
License: *PT00017590* Status: *Active* PIC: *No*

ROMINA PEREZ GARCES
License: *019471* Status: *Active* PIC: *No*

Douglas w Beck II
License: *PT00365846* Status: *Active* PIC: *No*

CHAD JAMES FORINASH
License: *014827* Status: *Active* PIC: *Yes*

CRYSTAL C OWENS

Pharmacist and Interns *(continued)*

License: *014248* Status: *Active* PIC: *No*

LESLIE SCOTT MILLER
License: *013252* Status: *Active* PIC: *No*

ASHLEY BARNETT
License: *PT00371155* Status: *Active* PIC: *No*

KELLY MARIE JOHNSON
License: *014496* Status: *Active* PIC: *No*

Megan D O'Bryan
License: *PT00375296* Status: *Active* PIC: *No*

KATIE M KOCIEMBA
License: *016202* Status: *Active* PIC: *No*

Naysa A Marrero Santiago
License: *PT00357255* Status: *Active* PIC: *No*

Whitney Barnes
License: *PT00035436* Status: *Active* PIC: *No*

Hailee Stebbins
License: *PT00364125* Status: *Active* PIC: *No*

David C Hylton
License: *PT00359531* Status: *Active* PIC: *No*

BRITTANY N BANKS
License: *PT00029752* Status: *Active* PIC: *No*

La'Kayla Crawford
License: *PT00355881* Status: *Active* PIC: *No*

DAVID CARL HILEMAN
License: *012185* Status: *Active* PIC: *No*

Pharmacy Area

Reference Material (201 KAR 2:090) Section 1	*Compliant*
Equipment (201 KAR 2:090) Section 2	*Compliant*
Security and Control (201 KAR 2:100)	*Compliant*

Pharmacy Area *(continued)*

Sanitation (201 KAR 2:180)	*Compliant*
Refrigeration (201 KAR 2:090) Section 2 (1)(h)	*Compliant*
Drug Storage (201 KAR 2:180) Section 5	*Compliant*
Exclusive Compounding Area (KRS 217.055(2)) 201 KAR 2:180 Section 1	*N/A*

Comments

do not compound

General

Valid R.Ph License Displayed (KRS 315.110) (2)	*Compliant*
Valid Pharmacy Permit (KRS 315.035) and KRS 315.020 (add PIC info)	*Compliant*
Valid Intern Registration Identification Card (201 KAR 2:040) Section 4	*Not Inspected*
Valid Technician Registration Displayed: KRS 315.138 (2)	*Compliant*
Records/Computer Records (201 KAR 2:170)	*Compliant*
Syringe/Needle Register (KRS 217.177)	*N/A*
Outdated Stock Removed (KRS 217.055)	*Compliant*
Prescription Labeling Requirements (KRS 217.065)	*Compliant*

Comments

discussed process for FDA required medication guides

Pseudoephedrine Log (KRS 218A.1437) KRS 218A. 1446	*N/A*
Collaborative Care Agreements (201 KAR 2:220)	*Not Inspected*
Board Authorized Protocols (201 KAR 2:380)	*Not Inspected*

Generic Substitution

Additional Prescription Recordkeeping (KRS 217.822) and 201 KAR 2:280	*Compliant*
Generic Drug Sign Posted (KRS 217.830)	*Compliant*
Pamphlet (KRS 217.896)	*Not Inspected*

Controlled Substances

CII Prescription Requirements (KRS 218A.180) and 902 KAR 55:105	*N/A*
Oral CIII-V Prescription Requirements (KRS 218A.180) and 902 KAR 55:105	*Not Inspected*
Written CIII-V Prescription Requirements (KRS 218A.180) and 902 KAR 55:105	*Not Inspected*
Purchase Records/DEA 222 Forms (KRS 218A.200)	*Compliant*
KASPER (902 KAR 55:105, 110)	*Compliant*
CII-V Filing Requirements - Prescription/Po: 21 (CFR 1304.04)	*Compliant*
Exempt CV Register (KRS 218A.190)	*N/A*
Biennial Inventory Complete (21 CFR 1304.11) and KRS 218A. 200 (7)	*Compliant*
Power-of-Attorney Current 21 (CFR 1305.05)	*Compliant*
Inform Public of Proper and Safe Disposal of Controlled Substances (KRS 218A.170(3)(4))	***Noncompliant***

Comments

provide informationon safe disposal

Patient Records/Counseling

Patient Record System (201 KAR 2:210)	*Compliant*
Patient Recordkeeping (201 KAR 2:210)	*Compliant*
Drug Utilization Review (201 KAR 2:210)	*Compliant*
Patient Counseling (201 KAR 2:210)	***Noncompliant***

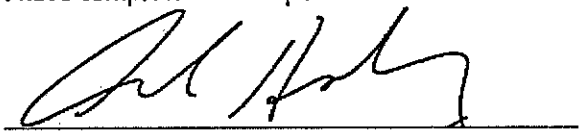
Comments

written counseling information not consistently provided

Refused Offers Documented (201 KAR 2:210)	*N/A*

Inspector's Signature

I have completed this inspection in accordance with the statutes and administrative codes.



Inspector: *Amanda Harding*

Pharmacist's Signature

I have read and understand the statutes and administrative codes. I acknowledge that the items noted in this report have been discussed with me. I understand that if I disagree with any of the deficiencies cited, that I have the right to refute them on this report or and other form that I choose to send to the department.

Pharmacist: *CHAD FORINASH*

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Resident Pharmacy

EFFECTIVE DATE: 05/12/2017

NUMBER: P07840

EXPIRATION DATE: 06/30/2025

PIC: CHAD JAMES FORINASH

Issued to:
PHARMACORD

11001 BLUEGRASS PARKWAY
STE 200
LOUISVILLE, KY 40299

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address. and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

rx@pharmacord.com

Kentucky Board of Pharmacy

3287

Print

License Verification Details

Detail for License Number P07840

PHARMACORD

11001 BLUEGRASS PARKWAY
STE 200
LOUISVILLE, KY 40299

Kentucky Board of Pharmacy

State Office Building Annex, Ste 300
125 Holmes Street
Frankfort, KY 40601

License Information

Expiration Date	6/30/2025
Effective Date	5/12/2017
Status of Permit	Active
Board Action	No
Case Number(s)	

The Kentucky Board of Pharmacy website is considered primary source verification and is actually the preferred method of licensure verification. Both JCAHO and the Cabinet for Health and Family Services, Office of the Inspector General, consider verification through the website as evidence of licensure.

12:19 PM
6/10/2024

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP6777215	03-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-02-2023

PHARMACORD
11001 BLUEGRASS PKWY STE 200
LOUISVILLE, KY 402992368

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP6777215	03-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
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PHARMACORD
11001 BLUEGRASS PKWY STE 200
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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PharmaCord

Pharmacy/Wholesaler License # (if applicable) PH03768

Physical Address 11001 Bluegrass Parkway, Suite 200

City Louisville State KY Zip 40299

Mailing Address (if different from physical address) Same as Above

City _____ State _____ Zip _____

Telephone 502-805-3530 Website www.pharmacord.com

Licensing Company Email rx@pharmacord.com

Section 2: Personal Information

First Chad Middle James Last Forinash

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 11001 Bluegrass Parkway, Suite 200

City Louisville State KY Zip 40299

Telephone 502-805-3415 Email chad@pharmacord.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Univ of Colorado		01/04-05/11	
Address	City	State	Zip
12850 E Montview Blvd	Aurora	CO	80045
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Webster University		01/04-10-07	
Address	City	State	Zip
470 E Lockwood Ave	St. Louis	MO	63119
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
St. Louis College of Pharmacy		08/98-08/03	
Address	City	State	Zip
4588 Parkview Place	St. Louis	MO	63110
Diploma/Degree obtained, if any			
B.S. Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Arcadia Valley HS		08/94-05/98	
Address	City	State	Zip
520 Park Dr	Ironton	MO	63650
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/17-Present	[redacted]uckaho Road	Louisville	KY	40207
10/15-07/17	[redacted]Russell Blvd	St. Louis	MO	63110
07/05-10/15	[redacted]olgate Dr	Saint Charles	MO	63303
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
PharmaCord, LLC			05/17-Present	
Business Address		City	State	Zip
11001 Bluegrass Parkway, Suite 200		Louisville	KY	40299
Phone	Title		Number of Employed Hours	
502-805-3530	Sr. Director Pharmacy & Clinical Services		14560	
Description of Duties				
-Prescription verification -Facility management				

Business Name			From - To (MM/YY – MM/YY)	
Dohmen Life Sciences			02/13-05/17	
Business Address		City	State	Zip
17877 Chesterfield Airport Rd		Chesterfield	AR	71602
Phone	Title		Number of Employed Hours	
636-519-2400	VP Pharmacy Services		8320	
Description of Duties				
-Prescription verification -Facility management				

Business Name			From - To (MM/YY – MM/YY)	
PharmaCorr/Corizon Health			10/11-01/13	
Business Address		City	State	Zip
6814 Princeton Pike		Pine Bluff	AR	71602
Phone	Title		Number of Employed Hours	
888-321-7774	Regional Pharmacy Manager		2080	
Description of Duties				
-Prescription verification -Facility management				

Business Name			From - To (MM/YY – MM/YY)	
The Corner Pharmacy Holdings, Inc.			05/10-12/11	
Business Address		City	State	Zip
12255 Depaul Drive, Suite 600		Bridgeton	MO	63044
Phone	Title		Number of Employed Hours	
314-209-5100	Pharmacist-in-Charge		2080	
Description of Duties				
-Prescription verification -Facility management				

Business Name			From - To (MM/YY – MM/YY)	
SSM Health Care			10/03-12/11	
Business Address		City	State	Zip
6420 Clayton Rd		Richmond Heights	MO	63117
Phone	Title		Number of Employed Hours	
314-768-8000	PRN Staff Pharmacist		500	
Description of Duties				
-Prescription verification				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Express Scripts			10/03-12/07
Business Address	City	State	Zip
1 Express Way	St. Louis	MO	63121
Phone	Title	Number of Employed Hours	
800-711-5672	Pharmacy Compliance Auditor; Manager, Clinical Prgm's	8320	
Description of Duties			
-Prescription verification -Medicare Part D Manager -Compliance auditor			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Chad Forinash, **certify that as the designated representative for**

PharmaCord,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Chad Forinash

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-21-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Chad Forinash

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 6-21-24

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Jefferson

I, Chad Forinash, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 6-21-24

Subscribed and Sworn to before me this 21 day of June.

Suzannah R. Clark

Notary Public Signature

SUZANNAH RHEA CLARK
Notary Public
Commonwealth of Kentucky
Commission Number KYNP52598
My Commission Expires Jul 12, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PharmaCord

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03768

Physical Address 11001 Bluegrass Parkway, Suite 200

City Louisville State KY Zip 40299

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 502-805-3530 Website www.pharmacord.com

Licensing Company Email rx@pharmacord.com

Section 2: Personal Information

First Nitin Middle _____ Last Sahney

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addres[redacted]Hilton Dr

City Jeffersonville State IN Zip 47130

Telephone 502-805-3450 Email nitin@pharmacord.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Clarion University of Pennsylvania		1988-1990	
Address	**City**	**State**	**Zip**
909 E Wood St.	Clarion	PA	16214
Diploma/Degree obtained, if any			
Master in Business			
School Name		**From - To (MM/YY – MM/YY)**	
Panjab University		1981-1986	
Address	**City**	**State**	**Zip**
Panjab University	Chandigarh	India	
Diploma/Degree obtained, if any			
Under Grad			
School Name		**From - To (MM/YY – MM/YY)**	
Doon School Boarding School for Boys		1972-1981	
Address	**City**	**State**	**Zip**
Mall Road	Dehradun	India	248003
Diploma/Degree obtained, if any			
Elementary through H.S. Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/22-Present	[redacted]Valeros Court	Palm Beach Garden	FL	33418
03/16-09/22	[redacted]Harrods Glen Drive	Prospect	KY	40059
08/13-03/16	[redacted]Eustisfarm Lane	Indian Hill	OH	45243
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
PharmaCord, LLC			01/17-CURRENT	
Business Address		**City**	**State**	**Zip**
11001 Bluegrass Parkway, Suite 200		Louisville	KY	40299
Phone	**Title**			
	Founder & CEO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Retired			08/15-01/17	
Business Address		**City**	**State**	**Zip**
		Louisville	KY	
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Omnicare Inc			11/10-08/15	
Business Address		**City**	**State**	**Zip**
		Cincinnati	OH	
Phone	**Title**			
	President/COO/CEO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Healthcare Investment Fund Managements			01/08-11/10	
Business Address		**City**	**State**	**Zip**
		Louisville	KY	
Phone	**Title**			
	Advisor			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
RxCrossroads			10/01-12/07	
Business Address		**City**	**State**	**Zip**
		Louisville	KY	
Phone	**Title**			
	Founder & CEO			
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)
Cardinal Health		07/93-09/01
Business Address	City: Columbus	State: OH / Zip
Phone	Title: GM	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
N/A		
Business Address	City / State / Zip	
Phone	Title	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
N/A		
Business Address	City / State / Zip	
Phone	Title	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
N/A		
Business Address	City / State / Zip	
Phone	Title	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
N/A		
Business Address	City / State / Zip	
Phone	Title	
Description of Duties		

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nitin Sahney

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-18-24

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Jefferson

I, Nitin Sahney, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-18-24

Date

Subscribed and Sworn to before me this 18 day of June 2024.

Notary Public Signature

SUZANNAH RHEA CLARK
Notary Public
Commonwealth of Kentucky
Commission Number KYNP52598
My Commission Expires Jul 12, 2026

(Seal)

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: - Independent - mail-order - Non-Sterile Compounding	☑ Retail/Community ☑ Dangerous drugs ☑ Controlled substances DEA #: FP8126725 ☑ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday (RPh on call 9am-12pm)	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Physicians Preference Pharmacy International, LLC

Physical Address: 20214 Braidwood Drive, Ste. 140

City: Katy State: TX Zip: 77450

Mailing Address (if different from physical address): Same

City: _____ State: _____ Zip: _____

Telephone: 281-828-9088 Toll Free # (NAC 639.708, NRS 639.23286): 877-640-5248

Fax: 281-828-9669 Contact Email: kim.bennett@hotzepharmacy.com

Website: physicianspreferenceRx.com

Nevada Business License # (if applicable) NV20191115226

Supervising/Managing Pharmacist Name (NRS 639.220): Kimberly Baldwin Bennett

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24127

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kimberly Baldwin Bennett	NV Pharmacist Registration #: 24127
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): Medicus Rx Holdings, LLC

Corporation/Organization Name: Physicians Preference Pharmacy International, LLC

Mailing Address: 20214 Braidwood Drive, Ste 140

City: Katy State: TX Zip: 77450

Telephone: 281-828-9088 Email: kim.bonnette@hotzepharmacy.com

Contact Person Name: Kimberly Bonnett

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for Physicians Preference Pharmacy Int'l, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Kimberly Baldwin Bennett, R.Ph.
Print Name of Authorized Person

Kimberly B. Bennett, RPh
Original signature of Authorized Person (copies or stamps not accepted)

04/08/2024
Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Kimberly Baldwin Bennett hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for Physicians Preference Pharmacy Dth, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Kimberly B. Bennett, RPh
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 11th day of April, 2024

Notary Public

APRIL MARTINEZ
Notary Public, State of Texas
Comm. Expires 01-26-2026
Notary ID 131425279

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kimberly Baldwin Bennett, RPh

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Kimberly B. Bennett, RPh

Original signature of Authorized Person (copies or stamps not accepted)

04/08/2024

Date

Board Use Only	Date Received: 4/17/24	Amount: $500 - CC



This certifies that the pharmacy named below is hereby licensed to operate as a Class **A** pharmacy.

License No. **32372** Expiration Date: **12/31/2024**

Balances: **13**

PHYSICIANS PREFERENCE PHARMACY INTERNATIONAL LLC
20214 BRAIDWOOD DR STE 140
KATY TX 77450



Timothy L. Tucker, Pharm.D.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP8126725	03-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-03-2022

PHYSICIANS PREFERENCE PHARMACY INTERNATIONAL, LLC
20214 BRAIDWOOD DR STE 140
KATY, TX 774502142

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP8126725	03-31-2025	$888

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20214 BRAIDWOOD DR STE 140
KATY, TX 774502142

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Form DEA-223 (9/2016)

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *PHYSICIANS PREFERENCE PHARMACY INTERNATIONAL LLC*
License Number: *32372*
Address: *20214 BRAIDWOOD DR STE 140, KATY, TX 77450*
Phone: *(281) 828-9088*
Email:
Class of License: *A*
License Expiration: *12/31/2024*
DEA #: *FP8126725*
DEA Expiration: *03/31/2025*

Inspection Information

Type: *Compliance*
Purpose: *Licensee Request*
Date: *02/01/2024*
Arrival Time: *11:30 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Kimberly Bennett

Kimberly Bennett PIC 35871

Witness

Keya Henry

Keya Henry

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *PHYSICIANS PREFERENCE PHARMACY INTERNATIONAL LLC*
License Number: *32372*
Address: *20214 BRAIDWOOD DR STE 140, KATY, TX 77450*
Phone: *(281) 828-9088*
Email:
Class of License: *A*
License Expiration: *12/31/2024*
DEA #: *FP8126725*
DEA Expiration: *03/31/2025*

Inspection Information

Type: *Compliance*
Purpose: *Licensee Request*
Date: *02/01/2024*
Arrival Time: *11:30 AM*

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1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Kimberly Bennett

Kimberly Bennett PIC 35871

Witness

Keya Henry

Keya Henry

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *PHYSICIANS PREFERENCE PHARMACY INTERNATIONAL LLC* License Number: *32372*

Class of License: *A*

Inspection Information

Type: *Compliance* Purpose: *Licensee Request*

Date: *02/01/2024* Arrival Time: *11:30 AM* Departure Time: *4:45 PM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Satisfactory*
17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Satisfactory*

Comment

Annual controlled substance inventory completed on: 05/01/2023 (OOB).

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Satisfactory*
34. Notifications	*Satisfactory*

76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean	*Satisfactory*
04. Balance inspection	*Satisfactory*

Comment

Number of balances: 13

05. Equipment Inspection	*Satisfactory*
07. Security	*Satisfactory*
08. Environment	*Satisfactory*
48. Drugs (procurement, temperature, security, out-of-date, samples)	*Satisfactory*
90. TSBP complaint notification	*Satisfactory*

Controlled Substances

10. Prescriptions separated	*Satisfactory*
24. Theft/Loss	*Satisfactory*

Comment

Theft or loss reported on 10/20/2022

26. Controlled substance prescription compliance	*Satisfactory*
30. Controlled substance invoices dated/initialed by pharmacist	*Satisfactory*
35. Controlled substance invoices separated	*Satisfactory*
46. Drug distribution	*Satisfactory*
53. Possession of controlled substances	*Satisfactory*
57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Satisfactory*
45. Proper dispensing/labeling	*Satisfactory*
54. Proper prepackaging procedures	*Satisfactory*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Satisfactory*
61. Supervision of supportive personnel	*Not Applicable*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Satisfactory*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Satisfactory*
56. Prescription transfers	*Satisfactory*
67. Written drug information provided	*Satisfactory*
80. Patient counseling	*Satisfactory*
82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*
86. Absence of pharmacist records	*Satisfactory*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Satisfactory*
92. Automated dispensing policy & procedures/SOPs	*Satisfactory*

Non-Sterile Compounding

38. Area for non-sterile compounding	*Satisfoctory*
43. Records for non-sterile compounding	*Satisfactory*

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and

- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).

Kimberly Bennett

Keya Henry

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

KB — I am the Pharmacist-in-Charge (PIC) of *PHYSICIANS PREFERENCE PHARMACY INTERNATIONAL LLC*, pharmacy license number *32372*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *02/01/2024*.

KB — I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

KB — I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

N/A — If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

KB — I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: K Bennett — Date: *02/01/2024*

Printed Name: *Kimberly Bennett* — License No.(if applicable): *35871*

Texas State Board of Pharmacy

"Red Flags" Checklist for Pharmacies

YOU MIGHT BE A PILL MILL IF...

Check all that apply:

	(1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy
	(2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume.
	(3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs.
	(4) The prescriptions for controlled substances contain nonspecific or no diagnoses.
	(5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities.
	(6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions.
	(7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms.
	(8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy.
	(9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate.
	(10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants.
	(11) Drugs prescribed are inconsistent with the prescriber's area of practice.
	(12) The prescriber of the drugs is located a significant distance from your pharmacy.
	(13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action.
	(14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies.
	(15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office.
	(16) Multiple persons with the same address present prescriptions from the same prescriber.
	(17) Persons pay with cash or credit card more often than through insurance.
	(18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy).
	(19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies.
	(20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders.
	(21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday.
	(22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems.
	(23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility).

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

Updated 2/2018

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Physicians Preference Pharmacy International, LLC (file number 803123353), a Domestic Limited Liability Company (LLC), was filed in this office on September 20, 2018.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on April 11, 2024.

Jane Nelson
Secretary of State

PHYSICIANS
PREFERENCE
PHARMACY

RECEIVED
4/17/24

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy #206
Reno, NV 89521

April 8, 2024

Dear Licensing Director:

Please find enclosed the non-resident pharmacy application for Physicians Preference Pharmacy International, LLC. We previously held licensure in Nevada for many years, but closed our license due to the mandate that all pharmacists hold licensure in Nevada, as it just was not feasible for our business. Our previous license number was PH01991.

We are reapplying for licensure now that the pharmacist requirement has changed. I am the managing pharmacist, and I hold NV licensure (24127). Our facility and ownership have not changed in the time since our NV licensure closure, nor have we added or cancelled any of our services. We are operating in the same manner and are still PCAB-accredited.

Sincerely,

Kimberly B Bennett, RPh

Kimberly Baldwin Bennett, R.Ph.
Pharmacist in Charge

20214 Braidwood Drive, Suite 140, Katy, Texas 77450
281.828.9088 toll free 877.640.5248

PhysiciansPreferenceRX.com

TEXAS STATE BOARD OF PHARMACY

April 11, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

RE: Physicians Preference Pharmacy International, LLC (Texas Pharmacy License #32372)

Hello:

On April 9, 2024, the Texas State Board of Pharmacy (TSBP) received a request for information regarding the above-described licensee.

We have enclosed documents responsive to the request.

The Texas State Board of Pharmacy would like to request your assistance in assessing the customer service you received. We appreciate your time and input. Please use https://www.surveymonkey.com/r/WYGCJKS to access the survey.

If you need additional information, please contact Renee Slaughter, Senior Administrative Assistant, at (512) 305-8028.

Sincerely,

Open Records
Texas State Board of Pharmacy

TEXAS STATE BOARD OF PHARMACY

Re:	Physicians Preference Pharmacy International, LLC
Address:	20214 Braidwood Drive, Suite 140 Katy, Texas 77450
License No.:	32372
Date Issued:	December 10, 2018
Licensure Status:	Active
Expiration Date:	December 31, 2024
Type of Pharmacy:	Community – Class A
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Physicians Preference Pharmacy International, LLC (Texas Pharmacy License #32372) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy

April 11, 2024
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: Physicians Preference Pharmacy International, LLC

Address: 20214 Braidwood Drive, Ste 140

City: Katy State: TX Zip: 77450

I hereby authorize the TX State Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant Kimberly B. Bennett, RPh (PIC)

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
32372	Active	December 10, 2018	December 31, 2024

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☑ No (see attached)	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☑ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☑ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☑ No (see attached)
Has applicant met all licensing requirements of your state? (If no, please explain)	☑ Yes ☐

Signature of State Official	Title	State	Date
Lauren D. Briggs	Deputy General Counsel	Texas	April 11, 2024

Physicians Preference Pharmacy International, LLC.
FEIN: 83-2015939

Ownership Breakdown:

Sole Member (100%):
Medicus Rx Holdings, LLC
FEIN: 83-2147123
20214 Braidwood Drive, Suite 140
Katy, Texas 77450
Steven F. Hotze, President and Manager

Managing Officers:

Steven F. Hotze
President and Manager
[redacted] Russet Drive
Houston, TX 77056
[redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Physicians Preference Pharmacy International, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 20214 Braidwood Drive, Ste. 140

City Katy State TX Zip 77450

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 877-640-5248 Website Physicians Preference Rx. com

Licensing Company Email kim.bennett@hotzepharmacy.com

Section 2: Personal Information

First Kimberly Middle Baldwin Last Bennett

Alias(es, nicknames, name changes, etc.) Kimberly Beth Baldwin; Kimberly Baldwin Haddock

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Cloverfield Dr.

City Katy State TX Zip 77494

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 689A.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Houston - College of Pharmacy		09/93 – 12/95	
Address	**City**	**State**	**Zip**
Health 2, 4349 MLK Blvd, Room 3044	Houston	TX	77204
Diploma/Degree obtained, if any			
B.S. Pharm			

School Name		From - To (MM/YY – MM/YY)	
Lamar University		09/87 – 12/91	
Address	**City**	**State**	**Zip**
4400 MLK Blvd, PO Box 10009	Beaumont	TX	77710
Diploma/Degree obtained, if any			
B.S. & Psychology			

School Name		From - To (MM/YY – MM/YY)	
French High School / Central High School		09/83 – 05/87	
Address	**City**	**State**	**Zip**
88 Jaguar Drive	Beaumont	TX	77702
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/21 – current	[redacted] Cloverfield Drive	Katy	TX	77494
05/16 – 07/21	[redacted] Crested Lark Ct	Katy	TX	77450
09/13 – 05/16	[redacted] Bellrows Bend Dr	Katy	TX	77450

Section 7- A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record-keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above:

Business Name		From - To (MM/YY – MM/YY)
Physicians Preference Pharmacy International, LLC		07/04 – current
Business Address	**City**	**State / Zip**
20214 Braidwood Drive, Ste. 140	Katy	TX 77450
Phone	**Title**	**Number of Employed Hours**
281-828-9088	Pharmacist in Charge	>40,000
Description of Duties		
Pharmacist in Charge / Director of Business operations		Dispensing, record keeping, in charge of operations, integrity of drug stock, etc.

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**
Description of Duties		

Continue on next page if additional space is needed.

Section 8- Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Kimberly Baldwin Bennett, **certify that as the designated representative for** Physicians Preference Pharmacy International, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KBB I am at least 21 years of age;
3. KBB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KBB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KBB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KBB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KBB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kimberly Baldwin Bennett
Print Name (First, Last)

Kimberly B. Bennett, RPh
Original Signature (electronic, copies or stamps not accepted)

07/10/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kimberly Baldwin Bennett
Print Name (First, Last)

Kimberly B Bennett, PA
Original Signature (electronic, copies or stamps not accepted)

07/10/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Harris

I, Kimberly Baldwin Bennett, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Kimberly B. Bennett, PA
Original Signature

07/10/2024
Date

Subscribed and Sworn to before me this 10th day of July 2024

April Martinez
Notary Public Signature

APRIL MARTINEZ
Notary Public, State of Texas
Comm. Expires 01-26-2026
Notary ID 131425279

(Seal)

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 02326	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Ridgeway Pharmacy, Ltd. dba Ridgeway Pharmacy Closed Door

Physical Address: 2824 US HWY 93N

City: Victor State: MT Zip: 59875

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 406-642-6040 Toll Free # (NAC 639.708, NRS 639.23286): 800-630-3214

Fax: 406-642-6050 Contact Email: CUSTOMERSERVICE@RIDGEWAYRX.COM

Website: Ridgeway.pharmacy

Nevada Business License # (if applicable) D094011

Supervising/Managing Pharmacist Name (NRS 639.220): Klinton Curtis / Cree Maloney

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): Klinton Curtis - 24118 (Temporary) / 24117

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: See attached.	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Not Applicable.	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Ridgeway Pharmacy, LTD.

Pharmacist and Technician List

Pharmacist Name	License Number	Hours per Week
Klinton Kyp Curtis	PHA-PHA-LIC-3548	40
Carly Maloney Hansen	PHA-PHA-LIC-11502	30
Cree C Maloney	PHA-PHA-LIC-62855	35
Candice Amsler Brilz	PHA-PHA-LIC-2982	35
Kaylene Rae Nelson	PHA-PHA-LIC-63207	30

Section 5: Publicly Traded Corporation

State of Incorporation: Not Applicable.

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Montana

Parent Company (if any): Ridgeway Holding Company, LLC

Corporation/Organization Name: Ridgeway Pharmacy, LTD. dba Ridgeway Pharmacy Closed Door

Mailing Address: 5000 Sawgrass Village Circle, Suite 4

City: Ponte Vedra Beach State: FL Zip: 32082

Telephone: Email: akoering@revive.health

Contact Person Name: Adam Koering

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: Not Applicable.

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Not Applicable.

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Fincancial Officer (title) for Ridgeway Pharmacy, LTD. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Adam Koering

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/12/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Klinton Curtis hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge (title) for Ridgeway Pharmacy, LTD. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 12 day of February 2024

Notary Public

CHRISTINA MOOREN
Notary Public for the
State of Montana
Residing at FLORENCE, MT
My Commission Expires
August 31, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adam Koering

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/12/24
Date

Board Use Only	Date Received: 4/3/24	Amount: $500 check 917316

Montana Department of
LABOR & INDUSTRY

Montana Department of Labor and Industry
Business Standards Division
301 South Park Avenue
Helena, MT 59620

Montana Board of Pharmacy
On-site Inspection Report

(Board use only)

License Number: PHA-PHR-LIC-1119	**Licensee Name:** RIDGEWAY PHARMACY CLOSED DOOR
Licensee Address and Phone Number: 2824 HWY 93 NORTH, VICTOR 406-642-6040	**Pharmacist-in-charge Name and Email:** Klinton "Kip" Curtis send report to: cmaloney@ridgewayrx.com
Inspection Date: 7-12-2023	**Inspector Name:** Genine Pitts, PharmD
Inspector E-mail: genine.pitts@mt.gov	**Inspector Phone:** (406) 431-1952
Inspection Type: ☐ **Initial** ☑ **Annual** ☐ **Re-Inspection**	**Inspection Status:** ☑ **Passed** ☐ **Failed** ☐ **Passed with Conditions**

Comments:

(Board use only)

1. Biennial controlled substance inventory needs to include the container size for each product (ie., 100 count bottle) and the number of bottles counted for each drug (ie., if there is 1 open bottle and 1 sealed bottle indicate 2 bottles). See 21 CFR 1304.11 for requirements.

Note that neither remote nor on-site Board inspections evaluate compliance with all requirements.

Links to REFERENCE information: ARM and MCA

Montana Department of
LABOR & INDUSTRY

Montana Board of Pharmacy Inspection Form – On-site
Community Pharmacy (PHR)

PHARMACY FACILITY

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Is the pharmacy orderly and clean?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.819(1)	Reviewed
Are the sanitation and equipment requirements met?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.819(2)	Reviewed
Are the security requirements of the pharmacy being met?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.814	Alarm, cameras, motion sensors
Is the mandated generic substitution sign displayed?	☐ YES ☑ NO ☐ NEEDS IMPROVEMENT	MCA 37-7-506	N/A closed door facility.
Does the pharmacy access a common electronic file?	☐ YES ☑ N/A	ARM 24.174.840	
If the pharmacy accesses a common electronic file, are the required notices in place?	☐ YES ☐ NO ☑ N/A	ARM 24.174.840(6)	
What pharmacy dispensing systems are utilized?	☐ N/A LIST>	ARM 24.174.1122	*Provide the name of the system or systems.* Guardian Rx
Are secure/unique login credentials kept for the pharmacy dispensing system?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.817(1)	System meets electronic records requirement. Readily retrievable daily log.
Is the pharmacy providing services to other facilities?	☐ YES LIST> ☑ N/A		*List:* N/A

Does the pharmacy utilize centralized filling and processing of drug order services?	☐YES LIST> ☑N/A		*List:* N/A
If the pharmacy is utilizing central filling and processing of drug orders, are all the requirements being met?	☐YES ☐NO ☐NEEDS IMPROVEMENT ☑N/A	ARM 24.174.823	
Does the pharmacy utilize remote processing of drug orders?	☑YES LIST> ☐N/A		*List:* Technicians from Idaho can data entry if needed (not used all of the time).
If the pharmacy is utilizing remote processing of drug orders, are all the security requirements being met?	☑YES ☐NO ☐NEEDS IMPROVEMENT ☐N/A	ARM 24.174.814 ARM 24.174.818	Software logs each employee's activity. Active Montana License.
Are outdated pharmaceuticals removed from stock and processed as required?	☑YES ☐NO ☐NEEDS IMPROVEMENT	ARM 24.174.2301(1)	No outdated product found during spot check.
Are the pharmaceuticals stored properly?	☑YES ☐NO ☐NEEDS IMPROVEMENT	ARM 24.174.819	Refrigerator is monitored electronically with alarms.
Can the system produce a drug audit?	☑YES ☐NO ☐NEEDS IMPROVEMENT	ARM 24.174.818(1)	
Is the pharmacy registered with the Montana Prescription Drug Registry (MPDR)?	☑YES ☐NO ☐N/A	ARM 24.174.1704(4)	Reviewed reporting 6-1-23 to 7-12-23
Is the pharmacy reporting required information to the MPDR by the close of the next business day?	☑YES ☐NO ☐N/A	ARM 24.174.1704(2)	
Is the Pharmacist-in-Charge (PIC) verifying the reported MPDR data as required?	☑YES ☐NO ☐NEEDS IMPROVEMENT	ARM 24.174.1704(6)	Also report to all registries across the country (licensed in all 50 states). Daily emails received verifying reporting.

Montana Department of
LABOR & INDUSTRY

LICENSING AND ENDORSEMENTS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Is the current facility license posted in a conspicuous place?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	MCA 37-7-321	Reviewed
Is the Montana Dangerous Drug registration current?	☑ YES ☐ NO ☐ N/A	ARM 24.174.1401(2)	Endorsement current
Are facility endorsements appropriate for facility?	☑ YES ☐ NO ☐ N/A		
Is the facility DEA registration current?	☑ YES ☐ NO ☐ N/A	21 CFR 1301.11	*Expiration date:* 4-30-25
Is the Combat Methamphetamine Self Certification current?	☐ YES ☐ NO ☑ N/A	21 CFR 1314.40	*Expiration date:* N/A
Do all pharmacists, interns, and technicians have an active license?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	MCA 37-7-301	Reviewed
Do the certified technicians have a current certification?	☑ YES ☐ NO	MCA 37-7-301	Reviewed
Has the PIC verified current employment and address information?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.301(34)	
Are endorsements on the pharmacists' licenses appropriate for site activities?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT		No immunizations given
Do the pharmacists have a current CPR certificates?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.503(3)	No immunizations given

Montana Department of
LABOR & INDUSTRY

DISPENSING ACTIVITIES

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Are the pharmacists identified?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	MCA 37-7-101(32)	Closed door facility
Is every prescription order evaluated by a pharmacist for safety and therapeutic appropriateness?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.1104(1)	Observed
Does the pharmacist perform prospective drug review?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.902	Observed
Does the pharmacist counsel patients as required?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.903	Patients call when they have questions and all prescriptions are mailed with patient information, even on refills.
Is there an appropriate counseling area?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.903(2)	*Describe the area or areas where counseling takes place.* Telephone consultations
Are the prescriptions properly labeled?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.832	Labels contain all requirements
Are you compounding at this facility?	☐ YES LIST> ☑ N/A		*List the types of compounding:* N/A
Are you compounding nonsterile pharmaceutical preparations?	☐ YES LIST> ☑ N/A		*List up to three examples:* N/A
Are policies and procedures in place to meet the requirements of USP 795 Compounding-Nonsterile pharmaceutical products?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.841(9)	N/A

Are you compounding sterile pharmaceutical preparations?	☐ YES LIST> ☑ N/A		*List up to three examples:* N/A
Are policies and procedures in place to meet the requirements of USP 797 Compounding-Sterile pharmaceutical products?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.841(9)	N/A
Are policies and procedures in place to meet the requirements of USP 800 Hazardous Drugs-Handling in Healthcare Settings?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.2301(1)	Not compounding HD
Is the assessment of risk for hazardous drugs current?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	USP 800 / ARM 24.174.2301(1)	
Is there a quality assurance program in place?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.407	*What is the last date of the program review?* URAC and VIPS error reporting policy and quarterly meetings.

PRESCRIPTION REQUIREMENTS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Do the prescriptions contain the required information?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.831	Reviewed
Are prescription transfers properly documented?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.835	Guardian Rx software
Do the Schedule III-V phoned in prescriptions contain the required information?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	21 CFR 1306.05	Reviewed requirement, no telephoned prescriptions found during spot check.

Montana Department of
LABOR & INDUSTRY

RECORD KEEPING

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Are the Power of Attorney forms in place for current staff to order controlled substances?	☑ YES ☐ NO ☐ N/A	21 CFR 1305.05	*How many individuals at the facility are authorized to order controlled substances?* 2 POAs Recommend revoking and removing old POAs from file.
Are the PIC agreements in place?	☑ YES ☐ NO	ARM 24.174.805	Owner is PIC
Are individual DEA CSOS key codes kept confidential?	☑ YES ☐ NO ☐ N/A	21 CFR 1311.30	Reviewed
Are DEA 222 forms properly executed?	☑ YES ☐ NO ☐ N/A	21 CFR 1305.12	Reviewed some Inmar returns and transfers to other pharmacies.
Is the DEA Biennial Inventory current, correctly formatted, and available?	☐ YES ☐ NO ☑ NEEDS IMPROVEMENT ☐ N/A	21 CFR 1304.11	Done 4-11-23 at end of business. Missing the bottle size (ie., 100 count) and the # of bottles. Reviewed the requirement with Cree.
Are the controlled substance invoices filed properly?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	21 CFR 1304.21	CII are filed separately, signed/dated when received.
Are Schedule II records filed separately?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	21 CFR 1304.04(h)1	Reviewed
Are controlled substance prescriptions filed properly?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	21 CFR 1304.04(h)1	CII separate, CIII-V with legend
Does the pharmacy maintain perpetual inventory on Schedule II drugs?	☑ YES ☐ NO ☐ N/A	ARM 24.174.814(1)	Reviewed manual log book

Is the perpetual inventory reconciled as required?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	ARM 24.174.814(1)	Biannual counts. Verified hydrocodone/apap 7.5/325mg and oxycodone 5mg.
Have there been any significant shortages or losses of controlled substances in the past year?	☐ YES ☑ N/A	21 CFR 1301.74(c)	
If so, was the loss reported to the DEA within 24 hours, the Board of Pharmacy, and law enforcement?	☐ YES ☐ NO ☑ N/A	21 CFR 1301.74(c) ARM 24.174.1411(3), (4)	*Date of loss:* *Date the Board was notified:*

PHARMACY TECHNICIANS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Is the Technician Utilization Plan accessible and being used?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	ARM 24.174.712	Reviewed
Has the Technician Utilization Plan been annually reviewed and current?	☑ YES ☐ NO ☐ N/A	MCA 37-7-308(1)	Reviewed on 3/1/23
Do the technicians and auxiliary staff understand their responsibilities and limitations?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	ARM 24.174.705	Did not observe technicians working outside of scope of practice.
Are the technicians and auxiliary staff properly identified?	☐ YES ☐ NO ☑ N/A	ARM 24.174.703(5)	Closed door facility, not required.
Are the technicians properly identifying themselves when answering the telephone?	☑ YES ☐ NO ☐ N/A	ARM 24.174.705(1)	Observed
What is the current technician ratio?	☐ YES ☐ NO ☑ N/A	ARM 24.174.711	*Describe the typical staffing levels.* 7:1 or 2 pharmacists.

Does the pharmacy operate with a technician variance approved by the Board?	☐YES ☐NO ☑N/A	ARM 24.174.711(3)	*What is the effective date and approved variance date?* *Approved variance:* *Approved Date:*
If an application for increased ratio has been requested, are the required documents in place?	☐YES ☐NO ☑N/A	ARM 24.174.711(4)	No longer necessary. Ratio was eliminated in 2022.

PHARMACY INTERNS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Does the preceptor/intern relationship meet requirements?	☑YES ☐NO ☐N/A	ARM 24.174.602	Intern license for Sarah Ekkelboom posted.

ADMINISTRATION OF VACCINES

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Does the pharmacy limit immunizations to the independent authority allowed in statute?	☐YES ☐NO ☑N/A	MCA 37-7-105	*What additional immunizations are allowed under a collaborative agreement?*
Are the required policies and procedures for the immunization program in place?	☐YES ☐NO ☐NEEDS IMPROVEMENT ☑N/A	ARM 24.174.503(4)	
Is there access to the CDC reference?	☐YES ☐NO ☑N/A	ARM 24.174.503(4)	
Are the required state sanctioned immunization records complete and maintained?	☐YES ☐NO ☐NEEDS IMPROVEMENT ☑N/A	MCA 37-7-105(4)	

COLLABORATIVE PRACTICE

		REFERENCE	CORRECTIVE ACTION/COMMENTS
List of current collaborative practice agreements:	☑ N/A LIST>		*List the type of agreement and the effective date.*
Have all participating staff signed the current collaborative practice agreements?	☐ YES ☐ NO ☑ N/A	ARM 24.174.524(2)	
Do the collaborative practice agreements include all requirements?	☐ YES ☐ NO ☑ N/A	ARM 24.174.524(2)	

TELEPHARMACY OPERATIONS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Does this pharmacy have a Telepharmacy endorsement?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1302(4)	*List the parent pharmacies and license numbers.*
Does the current staffing ratio at the Parent and the Telepharmacy sites meet the requirements?	☐ YES ☐ NO ☑ N/A	ARM 24.174.711	*Describe the typical staffing levels.*
Are the Telepharmacy prescription requirements met?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.1302(4)	
Are the required monthly visitation documents available?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.1302(4)	
Is the remote Telepharmacy site registered with the DEA?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1301.11	*Expiration Date:*
Are the DEA form requirements for Telepharmacy met?	☐ YES ☐ NO ☑ N/A	21 CFR 1305.12	

Are the DEA Registration/Requirements for Telepharmacy met?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1302(4)	
Are technician requirements for Telepharmacy met?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1302(4)	
Are the communication systems in place for Telepharmacy?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.1302(4)	*Describe the current communication system.*
Is the staff offering counseling at the remote Telepharmacy site?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.1302(4)	

State of Montana
Business Standards Division
Board of Pharmacy

PHA-PHR-LIC-1119

Status: **Active**
Expires: **11/30/2024**

This certificate verifies licensure as:

COMMUNITY PHARMACY

Person In Charge: KLINTON CURTIS

With endorsements of:
* *TECHNICIAN UTILIZATION PLAN*
* *DISPENSER OF DANGEROUS DRUGS*

RIDGEWAY PHARMACY CLOSED DOOR
2824 HWY 93 NORTH
VICTOR, MT 59875

Montana Department of
LABOR & INDUSTRY
RENEW OR VERIFY YOUR LICENSE AT:
https://ebiz.mt.gov/pol

Renew online at https://ebiz.mt.gov/pol by signing in with your username and password.

The renewal cycle for your board opens 60 days prior to the expiration date on your current license. Renew your license prior to your expiration date to avoid being charged a late fee(s).

Remember to maintain your online account information with a password, security question and a valid email address. You can update your account information by accessing the 'Account Management' link when logged in.

Montana Department of LABOR & INDUSTRY

ATTN: Notice of scheduled maintenance – Saturday, January 20th from 5 AM – 2 PM (MST).
During this time, the system may be unavailable. We apologize for any inconvenience.

State of Montana
Business Standards Division
Professional and Occupational Licensing Bureau
Board of Pharmacy

Click here for a disclaimer

Download as PDF | Print Page

License Information

Licensing Board/Program: Board of Pharmacy
License Type: Community Pharmacy License
License Number: PHA-PHR-LIC-1119
License Status: Active
License Expiration Date: 11/30/2024
License Issued Date: 06/04/2004

License Holder

Business Name: RIDGEWAY PHARMACY CLOSED DOOR
Name:
City, State Zip: VICTOR, MT 59875

Facility Information

Address: 2824 HWY 93 NORTH

City, State Zip: VICTOR, MT 59875

Relationships

Person In Charge: KLINTON CURTIS

Endorsements

With endorsements of:
* *TECHNICIAN UTILIZATION PLAN*
* *DISPENSER OF DANGEROUS DRUGS*

Public Documents

Our records show no public documentation for this licensee.

Discipline

Our records show no adverse information concerning this licensee.

Back

MONTANA

SECRETARY OF STATE

CERTIFICATE OF EXISTENCE

I, CHRISTI JACOBSEN, Secretary of State for the State of Montana, do hereby certify that:

RIDGEWAY PHARMACY, LTD.

duly filed its Articles of Incorporation for Domestic Profit Corporation in this office on February 26, 1998, and on that date was authorized to transact business in this state for a term of perpetual duration.

Payment is reflected in the records of the Secretary of State for all fees owed to the Secretary of State.

The most recent annual report has been filed with this office.

No articles of dissolution have been placed on the record in this office by said corporation and the records indicate the corporation is in good standing under the laws of the State of Montana.

The Secretary of State cannot certify that tax and penalties owed to this state on record with the Department of Revenue are current. Please contact the Department of Revenue at (406) 444-6900 to obtain information on the tax status.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of the State of Montana, at Helena, the Capital, this 25th day of January, 2024.

Christi Jacobsen
Montana Secretary of State

Certificate Number: 49852235

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Ridgeway Pharmacy, LTD. dba Ridgeway Pharmacy Closed Door

Pharmacy/Wholesaler License # (if applicable): PH02326

Physical Address: 2824 US HWY 93N

City: Victor State: MT Zip: 59875

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 406-642-6040 Website: Ridgeway.pharmacy

Licensing Company Email:

Section 2: Personal Information

First: Klinton Middle: Kyp Last: Curtis

Alias(es, nicknames, name changes, etc.): Kyp

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] US HWY 93N

City: Victor State: MT Zip: 59875

Telephone: [redacted] Email: kcurtis@ridgewayrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Montana		06/89-05/94	
Address	**City**	**State**	**Zip**
32 Campus Dr	Missoula	MT	59812
Diploma/Degree obtained, if any			
BS in pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Missoula Vo-tech		06/88-05/89	
Address	**City**	**State**	**Zip**
125 East Broadway	Missoula	MT	59812
Diploma/Degree obtained, if any			
Certified Respiratory Therapist			
School Name		**From - To (MM/YY – MM/YY)**	
Hamilton High School		08/82-05-86	
Address	**City**	**State**	**Zip**
327 Fairgrounds Rd	Hamilton	MT	59840
Diploma/Degree obtained, if any			
Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2001-present	[redacted] Syringa Ln	Victor	MT	59875
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Ridgeway Pharmacy, LTD. dba Ridgeway Pharmacy Closed Door		06/1998-present	
Business Address	**City**	**State**	**Zip**
2824 US HWY 93N	Victor	MT	59875
Phone	**Title**	**Number of Employed Hours**	
406-642-6040	Pharmacist-in-Charge	48,000	
Description of Duties			
PIC, Manager, Owner			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/12/201	03-15-2015	MT	Hamilton	Hamilton
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
TK-2014-0001375				
Reason/Charge				
Driving Under the Influence of Alcohol - 1st Offense/ Displaying License Plates Assigned to Another Vehicle.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Klinton Cour			N/A	
Name of Business/Industry/Entity				

Provide explanation below:

Klinton Curtis (Pharmacist-In-Charge)

State of Montana, 2014.

In November 2014, Mr. Klinton Curtis was arrested and charged with Driving under the Influence of Alcohol and Displaying a License Plate assigned to another vehicle. In March 2015, the two charges were dismissed, and Mr. Curtis plead guilty to a reckless driving charge. Mr. Curtis paid a fine and completed an informal probation. This matter is closed.

Klinton Curtis

Original Signature (electronic, copies or stamps not accepted)

2-13-24

Date

I, Klinton Curtis, **certify that as the designated representative for**

Ridgeway Pharmacy, LTD. dba Ridgeway Pharmacy Closed Door,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. x I am at least 21 years of age;
3. x I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. x I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. x I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. x I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. x I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Klinton Curtis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-12-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Klinton Curtis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Please have this section completed in the presence of a Notary Public.

State of Montana, ss. County of Ravalli

I, Klinton Curtis, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2.12.24

Date

Subscribed and Sworn to before me this 12 day of February.

Notary Public Signature

CHRISTINA MOOREN
Notary Public for the
State of Montana
Residing at FLORENCE, MT
My Commission Expires
August 31, 2027

(Seal)

HAMILTON [illegible]TY COURT, STATE OF MON[illegible]ANA Court of Record

SENTENCING ORDER – ORDER OF COMMITMENT

DEFENDANT

NAME:	KLINTON K CURTIS

The above Defendant was convicted on the 11 day of May, 2015, on charges of:

DOCKET #	[redacted]			
OFFENSE	Driving Under The Influ	~~Displaying License Plate~~	RECKLESS DRIVING	
MCA / ORD	61-8-401(1)(a) [1st]	61-3-301(3) [2]		
SENTENCE(S) IMPOSED				
FINE	$ / SS	$ / SS	$ 300 / SS	$ / SS
JAIL (DAYS)	/ SS	/ SS	90 / 90 SS	/ SS
RESTITUTION				

FINES:	300	1	DAYS CREDITED
SURCHARGES – STATE ($35): X	55	6	DAYS ORDERED SERVED BY:
SURCHARGE – V/W ($50) X			MINIMUM BLOCKS OF DAYS.
SURCHARGE – CT TECH FUND($5)X	5		ALL CASES: CONCURRENT CONSECUTIVE
SURCHARGE – CONTRACT FEE ($2)	~~X~~		
46-18-232 ($50 or actual)	50		
OSPD Costs			
TOTAL:	390		MONTHLY MINIMUM TODAY

TERMS AND CONDITIONS OF PROBATION/STAND ALONE ORDERS AND MANDATES

✓ Probation 6 month(s)	**DEFERRED IMPOSITION OF SENTENCE**
✓ Good Behavior/ No Violations of Laws or Sentencing Order	Charges:
Surrender License Plates and Registration By:	For: Months, Or Fine Sooner Paid
For: Days	Charges Dismissed:
✓ No Possession or Consumption of Alcohol. No Presence in Bars, Taverns, Casinos, etc.	Record Sealed:
✓ Alcohol/Drug Testing on Demand	Signature And Date:
✓ Appear in Court on Order.	24/7 MONITORING OR SCRAM SCRT 90 days for 24 FEES
✓ Correct Mailing Address On File Until Compliance With All Orders.	CDA FROM LAC 4/1 60 DAYS; FOLLOW ON TREATMENT AS RECOMMENDED BY LAC -- TIMELY WRITTEN EVIDENCE TO COURT
✓ **ADVISORIES:**	
Defendant May Request The Written Order be Conformed To Oral. Disobedience May Result In: Revocation Of Suspended Sentence; Suspension Of Driving Privileges; Punishment For Contempt as To Standing Orders And Mandates; Assignment Of Unpaid Debt To A Collection Agency.	FAXED 5-11-15 DISP
Informational Booking At Ravalli County Detention Center, And Booking Fee.	

HAMILTON CITY COURT CERTIFIED SEAL STATE OF MONTANA

Copies To: ☐ Defendant ☐ Defense Atty ☐ City Atty ☐ Jail ☐ HPD ☐ JPO ☐ APO ☐ RC[illegible] Dispatch

Defendant: [signature] Dated: May 15 Judge: [signature]

MINUTES OF APPEARANCE
HAMILTON CITY COURT
COURT OF RECORD

223 S Second St, Hamilton, MT 59840 (406) 363-6823

Defendant: KLINTON K CURTIS [redacted]

Address [redacted]

☑ The court determines the defendant is not under any disability that would prevent the court from proceeding with the arraignment ☐ Medication ☐ Alcohol, or other drug ☐ English language comprehension ☐ Illness ☐ Injury

Charge	M.C.A. / Ordinance	Plea	Potential Penalty
Driving Under The Influence Of Alcohol - 1st Offense TO BE DISMISSED	61-8-401(1)(a) [1st]	J dismissed on motion 2015	
Displaying License Plates Assigned To Another Vehicle TO BE DISMISSED	61-3-301(3) [2]		
RECKLESS DRIVING	61-8-301	G	90 day $300 3-7

Complaint filed by: SHAWN WILLIAMS Date of Offense: 11/21/2014

☑ Court finds probable cause to bring charge(s) ☐ Imprisonment is Not A Sentencing Option

☐ $250.00 OSPD costs or actual costs following trial ☐ Minimum $50 misdemeanor costs or actual costs

☑ The Court finds the defendant is advised of and understands:

☑ The right to a continuance before entering a plea.

☑ The nature of the charge for which the plea is offered;

☑ The mandatory minimum penalty, if any, and the maximum penalty provided by law, including the effect of any penalty enhancement provision or special probation restriction; and, the requirement to pay restitution.

☑ The right to be represented by an attorney at every stage of the proceeding and that, if necessary, an attorney may be assigned pursuant to the Montana Public Defender Act, Title 47, chapter 1;

☐ That the defendant has the right:

(i) to plead not guilty or to persist in that plea if it has already been made;
(ii) to be tried by a jury and at the trial to have the right to the assistance of counsel
(iii) to confront and cross-examine witnesses against the defendant;
(iv) not to be compelled to reveal personally incriminating information; and,
(v) to appeal from a conviction after trial

☐ The Court finds the defendant is advised of and understands that, by a plea of guilty or no contest, the defendant waives the right to a trial.

☐ The Court finds the defendant is advised of and understands that conviction may result in loss of various rights regarding firearms, deportation from or exclusion from admission to the United States, or a denial of naturalization.

☑ The defendant having entered a plea or pleas as noted above, and the Court having determined there is a factual basis for each plea to a misdemeanor which may result in incarceration, each plea other than a not guilty plea is accepted and there will be no further trial of any kind.

☐ The Court finds that each plea, other than a plea of not guilty, is made knowingly and voluntarily and not the result of threats or promises apart from a plea agreement.

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FV2997128 ☒ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Valiant Pharmacy Holdings, LLC dba Valiant Compounding Pharmacy

Physical Address: 1274 Anna J. Stepp Dr.

City: Ypsilanti State: MI Zip: 48197

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 734-545-1117 Toll Free # (NAC 639.708, NRS 639.23286): 1-855-466-2583

Fax: 734-545-1119 Contact Email: crobertson@valiantrx.com

Website: www.valiantrx.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Romena Haddad, PharmD

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24171

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Romena Haddad, Pharm D	NV Pharmacist Registration #: 24171
Name: Eihab Z. Swidan, Pharm D	NV Pharmacist Registration #: N/A
Name: Hossein A. Smidi, RPh	NV Pharmacist Registration #: n/A
Name: Jenifer Choi, Pharm D	NV Pharmacist Registration #: n/A
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Valiant Pharmacy Holdings, LLC

Mailing Address: 1274 Anna J. Stepp Dr.

City: Ypsilanti State: MI Zip: 48197

Telephone: 734-545-1117 Email: eswidan@valiantrx.com

Contact Person Name: Eihab Z. Swidan, Pharm D, CEO

Please check type of partnership (NAC 639.214) ☒ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Valiant Pharmacy Holdings, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Eihab Z. Swidan

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/5/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Eihab Z. Swidan hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for Valiant Pharmacy Holding, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 5th day of June, 20 24

Christine Robertson
Notary Public

CHRISTINE ROBERTSON
NOTARY PUBLIC, STATE OF MI
COUNTY OF LIVINGSTON
MY COMMISSION EXPIRES Sep 8, 2029
ACTING IN COUNTY OF Washtenaw

CHRISTINE ROBERTSON NOTARY PUBLIC LIVINGSTON CO., MICH.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Eihab Z. Swidan

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6/5/24

Date

Board Use Only	Date Received: 6/7/24	Amount: 500-CK-946251215 2

VALIANT
COMPOUNDING PHARMACY

1274 Anna J Stepp Rd. Ypsilanti, MI 48197
855-GOO-BLUE (855-466-2583) Toll Free Phone
855-445-1119 Toll Free Fax
info@valiantrx.com
www.valiantrx.com

Eihab Z Swidan, Pharm D, CEO
[redacted]Jack Pine Dr. Ypsilanti, MI 48197
[redacted]
eswidan@valiantrx.com

Hussein A. Smidi, RPh, Managing Partner
[redacted]Koss Dr. Macomb, MI 48044
[redacted]
hsmidi@valiantrx.com

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

VALIANT PHARMACY HOLDINGS, LLC

was validly authorized on December 13 , 2022, as a Michigan DOMESTIC LIMITED LIABILITY COMPANY and said limited liability company is validly in existence under the laws of this state and has satisfied its annual filing obligations.

This certificate is issued pursuant to the provisions of 1993 PA 23 to attest to the fact that the company is in good standing in Michigan as of this date.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS ★ Corporations, Securities & Commercial Licensing Bureau ★

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 4th day of March , 2024.

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24030031201

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

Bureau of Professional Licensing

Inspection History

License & Contact Information

License Holder: VALIANT PHARMACY HOLDINGS, LLC
License Type: Pharmacy License
License #: 5301013103 **License Status:** Active
Site Address: 1274 ANNA J STEPP, YPSILANTI, MI 48197
Contact Name / Type:
Contact Phone / Email:

List of All Inspections To-Date

Date	Inspection Type	Result	Inspector
06/01/2023	Pharmacy Application Inspection	Pass	Cathryn Broses
10/18/2023	Routine Inspection	Pass	Cathryn Broses

Inspection & Checklist Details

10/18/2023 Routine Inspection - PASS

Date	Inspection Type	Result	Inspector
10/18/2023	Routine Inspection	Pass	Cathryn Broses

Overall Inspection Comment: This inspection was performed by Cathryn Broses and Magan Gill.

Corrective actions were provided for the following deficiencies:

1. Hair exposed during compounding- improper garbing.
2. Technician licenses were not posted (fixed onsite).
3. Labeling and information provided to patients does not contain information on what product instability or contamination may look like.
4. No quarantine areas- need one for hazardous products, one for non-hazardous.
5. Repackaging of metformin should be one year beyond use date (BUD), not manufacturer's expiration date.
6. No repackaging records or logs.
7. No record of testing performed to monitor maintenance of cold chain for refrigerated products delivery.

CHECKLIST NAME: General Pharmacy Lic Insp

Checklist Item	Status
General Pharmacy Information	Yes

Is the current PIC the same individual listed on the pharmacy license in MiPlus: Yes
Traditional Retail: ☒
Open to the Public: ☒
Mail/Deliver in state: ☒
Mail/Deliver out-of-state: ☒
Veterinarian Pharmacy: ☒
Nonsterile Compounding: ☒
Nonsterile Hazardous Drug Compounding: ☒

PHARMACISTS

Pharmacist's Name: Eidan Swidan
License Number: 5302029783

Pharmacist's Name: Jennifer Choi
License Number: 5302040263

PHARMACY TECHNICIANS

Pharmacy Tech Name: Christine Robertson
License Number: 5303008994

Pharmacy Tech Name: Ola-anike Williams
License Number: 5303042557

Pharmacy Tech Name: Destinee Trevino
License Number: 5303030006

Pharmacy Tech Name: Hailey Buckner
License Number: 5303047003

Does the pharmacy mail or deliver filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy) to a provider or facility for administration to the patient?	No
Does the pharmacy provide prescription products to a provider or facility within the resident state for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? If yes, indicate if in complianze with state law.	No
Does the pharmacy provide prescription products for office use to other states. If so, list states.	No
Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No
Are pharmacy and pharmacy personnel licenses, permits, and registrations posted in customers' view (if required) and current? Provide relevant information if "no", such as closed-door pharmacy. **Comment:** Technician licenses were not posted, but was corrected while inspectors were still onsite.	No
Is the pharmacy operating under any exemption, restriction, waiver, or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? If yes, note the exemption or restriction.	No
Is pharmacy operating within the scope of any exemption, restriction, waiver or variance? If no, describe activities outside the scope.	No
Does the pharmacy hold any relevant accreditations or certifications? If so, indicate which in notes. **Comment:** PIC stated they expected PCAB accreditation soon.	No
Has the pharmacy held any accreditations or certifications in the past that have been rescinded or suspended? If yes, list and the reasons for discontinuation.	No
Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations posted or on file with the pharmacy current and in good standing/active?	Yes
Are all pharmacists, pharmacy interns, and pharmacy technicians on duty at the time of the inspection current and in good standing/active? (i.e. may be relief personnel not checked on posted licenses)	Yes
Is the PIC in full and actual charge and actively engaged in the practice of pharmacy at the location in compliance with resident state law?	Yes
How many hours (average) per week does the PIC work at this location? **Comment:** 40	Yes
Are acts restricted to pharmacists being only performed by pharmacists or pharmacy interns as allowed by state law?	Yes
Are pharmacists supervising pharmacy technicians and pharmacy interns as required by state law?	Yes
Are there written policies and procedures maintained by the pharmacy for the delegation of tasks to pharmacy technicians? **Comment:** Reviewed P/P and SOP books.	Yes
Are only pharmacy technicians, licensed, registered, or certified in compliance with state law, performing those acts that require such licensure. i.e. no unlicensed persons engaged in activities requiring a license?	Yes

Is there a process for periodic verification of validity of licenses?	Yes
Are pharmacists providing patient services that require additional training or certification appropriately trained and certified? Are the certifications current? (Immunization, CPR, MTM, etc.)	No
Does the pharmacy maintain the proper technician-to-pharmacist ratio, if applicable?	N/A
Does the pharmacy have a working security/alarm system in place that is in compliance with the laws and regulations of the resident state?	Yes
Is the ability to disable the alarm system restricted to pharmacists practicing at the location or other persons authorized by state law?	Yes
Are all prescription drugs stored within an enclosure that is lockable and protects the drug stock against unauthorized access at all times? If no, describe issue.	Yes
Is the means to unlock the enclosure limited to pharmacists practicing at the pharmacy and any other person authorized by state law?	Yes
Is the enclosure locked and the alarm system activated whenever the pharmacy is is closed for business and a pharmacist is not on the premises?	Yes
Are Schedule II controlled substances secured in a locked cabinet or safe or dispersed in accordance with state and federal law? If no, describe. **Comment:** no CII drugs	N/A
Is the pharmacy clean and sanitary, in good repair, and is there appropriate space for the prescription volume?	Yes
Does the pharmacy have a sink with hot and cold running water?	Yes
Is temperature in the drug storage area monitored and in compliance? If no, describe.	Yes
Is the temperature in the drug storage area within the USP range for controlled room temperature (20?-25?C or 68?-77 ? F)? Record the temperature at the time of inspection. **Comment:** 67.3, 71.8, 70.3, 69.1	Yes
Are the refrigerator and freezer restricted to drug products only (no food)?	Yes
The pharmacy has a process for how the refrigerator temperature is monitored for excursions 24/7. **Comment:** Electronically monitored.	Yes
Is the temperature in the refrigerator within the USP range (2?-8?C or 36?-46 ?F)? Record the temperature of the refrigerator at the time of inspection. **Comment:** 39.6, 36.9, 39.5, 46.4	Yes
The pharmacy has a process for how the freezer temperature is monitored for excursions 24/7.	Yes
Is the temperature in the freezer within the USP range (between ?25? to ?10?C or ?13? to 14 ?F)? Record the temperature of the freezer at the time of inspection.	N/A
Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes
Does the pharmacy have access to two references consistent with scope of pharmacy practice? **Comment:** drug information handbook, Veterinary handbook, Trissel's, more.	Yes
Are controlled substances only distributed to licensed entitites (other than those dispensed via prescriptions or to delivery agent per 333.7303(4)(b))?	N/A
Has there been a theft or loss? Was it reported to department as required per 338.3141(3)?	No
Does the pharmacy have the appropriate equipment, supplies and necessary drawers and cabinets for the practice of pharmacy?	Yes
Is the pharmacy a minimum of 150 square feet?	Yes
Does the pharmacy have a minimum of 10 square feet of free working space, plus an minimum additional 2 square feet of free working space for each pharmacist on duty?	Yes
Are the past two years of complete inventories of controlled substances available for review? Indicate the date of the last inventory. **Comment:** Pharmacy has only been opened since July/August 2023.	No

Is the inventory signed and dated by the pharmacist, and indicate whether taken at open or close of business?	N/A
Are the Schedule II drugs separated from other controlled substances schedules?	N/A
Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)? If yes, Audit 6 CS II Drugs. **Comment:** Only testosterone was in stock, count was correct. PIC stated they have the occasional benzodiazepine.	Yes
Is the Schedule II perpetual inventory log reconciled regularly in accordance with state law frequency? View the perpetual log and verify that reconciliation is taking place.	N/A
Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)? Report as required to board?	Yes
Does the pharmacy restrict ordering to only approved wholesale distributors or manufacturers licensed as required by state or federal law? **Comment:** Mck, Letco/Fargon, Medisca, PCCA, Republic Pharmaceuticals.	Yes
Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement) is received at the same time or before the product is received? Explain procedure if transaction data not received.	Yes
Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes
Is the receipt of Schedule II orders documented appropriately? DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and pharmacist performing verification.	N/A
Are invoices for controlled substances (Schedules II-V) that are received filed separately and are the invoices signed and dated upon receipt?	Yes
Are other invoices for receipt of prescription drugs (other than DEA controlled substances) maintained in accordance with state law?	Yes
Are records of returns to wholesale distributor, destruction of drugs on site if applicable, or of distributions to reverse distributors/drug destruction companies maintained. **Comment:** No returns yet.	N/A
Are two separate files for schedule II and schedule III-V invoices maintained?	Yes
Are CS invoices maintened for a minimum of 2 years?	Yes
Does the pharmacy maintain all required dispensing history including but not limited to prescription files on site? How long are records kept? If not on site, where? **Comment:** Kept electronically,	Yes
Other than electronic prescriptions, are hard copies of prescriptions, or for non-controlled substances electronic images, maintained at least two years from date of last dispensing for controlled substances, and in accordance with state law for other prescription drugs? **Comment:** All electronic.	N/A
Are electronic prescriptions maintained in accordance with state law and federal law for EPCS for the entire retention period and available on site or upon request by timelines established in law?	Yes
Are all dispensing records retrievable on site, on paper, or if automated, via computer monitor display, printout, or other data format, for the entire retention period required by state and federal law? **Comment:** PK software, and Lifefile.	Yes
Are partial dispensing records maintained in accordance with state and federal law? **Comment:** not reviewed at this visit.	N/A
Does the pharmacy maintain logs of OTC sales of restricted products in accordance with state and federal law, such as CV sales. **Comment:** PIC stated no OTC sales.	No
Are other records of distribution of prescription drugs maintained for distributions for office use, other pharmacies, etc.	Yes

Prescriptions dispensed appear to be pursuant to a valid patient-prescriber relationship.	Yes
Do pharmacists have access to the state prescription monitoring program?	Yes
Has the pharmacy dispensing system been approved/certified to receive electronic prescriptions for controlled substances?	Yes
If no, does the pharmacy receive electronic prescriptions for non-controlled substances? Note how they are received/recorded, i.e. converted to fax, otherwise reduced to writing, image maintained?	N/A
Are filled prescriptions verified for accuracy by a pharmacist, and verification documented, unless otherwise excepted by state law, prior to dispensing?	Yes
Are filled prescriptions appropriately labeled?	Yes
Do drugs dispensed in customized patient compliance packaging meet USP or state requirements for packaging and labeling?	N/A
Are prescriptions dispensed in child-resistant packaging unless a documented patient request or other exemption?	Yes
Confidentiality: Is access to the pharmacy computer system limited to appropriate personnel? Password protected, in a secured location, access limited by job type, access revoked as appropriate such as upon termination.	Yes
Does the pharmacy appropriately destroy PHI including labeled prescription vials?	Yes
Comment: Shred-It	
Mail/Delivery: If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes
Comment: Uses FedEx shipping boxes and packaging. No record of testing performed to monitor maintenance of cold chain for refrigerated products delivery.	
Off-Site Processes (central/remote fill/processing): Are any portions of the prescription processing (in the questions below) performed at a different location?	No
Is patient information (demographics and contact information) and profile information (allergies, disease states, etc) entered into the computer at another location?	No
Are prescriptions received by another location (including written, telephone, fax, electronic)?	No
Is prescription information entered into the computer system at another location?	No
Is the accuracy of the prescription information entered into the computer verified at another location?	No
Is any part of the DUR process (including assessing and acting on DUR alerts and warnings) performed at another location?	No
Are any prescriptions dispensed or sold from this facility filled at another location? If so, explain how the prescriptions are labeled including any identifier indicating it was filled at the other location.	No
If any of the above functions are performed at another location, is the other location under common ownership? If not commonly owned, explain if there is a central fill or other agreement in place.	N/A
If any of the above functions are performed at another location, is that location in a different state than this facility? If so, explain.	N/A
If any of the above functions are performed at another location, are there policies and procedures for the function that include maintaining records of the person(s) performing the function and accountability?	N/A
Is the other pharmacy and any personnel at another location licensed in this state? If so, place info into notes section	N/A
Off-Site Inventory: Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? Note name(s) of facilities or entities.	No
Do the emergency kits contain any compounded sterile products? If so, list.	N/A
Off-Site Inventory: Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? Note types and locations.	No
If so, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? Provide details.	N/A
Do the automated dispensing devices contain any compounded sterile products? If so, list.	N/A
Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, not just an offer)?	Yes
Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy?	Yes

PDMP: Does the pharmacy report dispensing of controlled substances to this state prescription drug monitoring program as required by state law?	Yes
Does the pharmacy report dispensing of controlled substances shipped into other states in accordance with those states' PDMP requirements.	Yes
Are all required records related to drugs distributed to and dispensed from automated dispensing devices maintained as required by state law documenting any required checks for accuracy of filling? **Comment:** no automated machines	N/A
Are all required records related to repackaging of drugs from manufacturer's containers into automated counting or dispensing devices, unit dose packaging, unit of use packaging, or other containers maintained in acordance with state law documenting personnel performing and checking the repackaging	No
Are all orders received when the pharmacy is open?	Yes
Does the pharmacy purchase any compounded products from other entities for dispensing to patients? If yes, describe.	No
Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? (for example, inventory or shrink report tools used, perpetual inventory in computer, etc)	Yes
Are incidents of diversion or resignation/termination of personnel for cause appropriately investigated and reported?	Yes
Are outdated, damaged, recalled or otherwise suspicious products segregated? (conduct a random check of shelves for outdated product)	Yes
Does the pharmacy use a reverse distributor? If so, indicate name of reverse distributor used. **Comment:** Have not yet decided on one.	No
Does the pharmacy repackage bulk containers of prescription medications into smaller containers for ease of use? **Comment:** Metformin.	Yes
Does the labeling indicate a beyond use date and repackaging date consistent with USP standards? **Comment:** Using manufacturer's expiration date and no repackaging log.	No
Does the pharmacy prepack bulk containers of prescription medications into unit-of-use quantities?	No
Does the labeling indiate a beyond use date and repackaging date consistent with USP standards?	N/A
Does the pharmacy return to stock prescription drugs that were filled but never picked up? **Comment:** Prescriptions are paid for before they are processed. Cash only, accepts no insurance.	No
Is the return maintained in the prescription vial, i.e. not returned to a stock bottle?	N/A
Does labeling indicate an appropriate beyond use date	Yes
Are processes in place to handle a drug recall?	Yes
Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No
Does the take-back program include controlled substances?	N/A
Does the pharmacy have a modified DEA registration for controlled substance take-back?	No
Drug repository program. Program for utilization of unused prescripitons drugs	No
Is the pharmacy dispensing medications which have previously left the control of pharmacy and pharmacist and have subsiquently been returned for resale or restocked?	No
Are there misbranded medications, IE: unlabeled vials, improperly labeled vials, manufacture bottles without or an obliterated lot number and expiration date?	No
Are there manufacturer prescription samples in the pharmacy?	No
Is patient profile data obtained and readily accessible to facilitate prospective drug utilization review prior to dispensing and for consultation with the prescriber, patient, or caregiver?	Yes
Is the accuracy of the information entered into the computer system checked and verified by a pharmacist?	Yes
Prospective drug utilization review is conducted prior to dispensing a new prescription or a refill in accordance with state and federal law.	Yes
Are DUR overrides/bypasses documented?	Yes
Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders?	Yes
The prescription is evaluated for legitimacy and there is a procedure followed when a prescription is suspected of being (or actually is) fraudulent?	Yes

Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, not just an offer)?	Yes
Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy?	Yes
Is there a mechanism for providing patient counseling for mailed or delivered prescriptions? **Comment:** Phone calls	Yes
Is patient counseling, the offer to counsel, or the refusal of patient counseling documented in compliance with state law?	Yes
Is the "Consumer Information Notice" displayed.	Yes
Does the pharmacy maintain 3 separate files for Schedule II, Schedule III-V and non-controlled substance prescriptions? **Comment:** 2 files. No CIIs	Yes
Is the generic supplier noted on the prescription?	Yes
Is the generic suppplier noted on the label and reciept?	Yes
Do telephone prescriptions indicate the sending and receiving individuals? **Comment:** Not evaluated at this visit.	N/A
Do transferred prescriptions have all the required information?	N/A
Is there a discard by date on the label?	Yes
Do controlled substance prescriptions indicate the quantitiy both written and numeric?	Yes
Do controlled substance prescriptions have a hand-written signature (or a valid, secure signature if sent electronically)?	Yes
Were any uncorrected deficiencies from a prior state inspection noted? If yes, indicate the repeat deficiencies. Attach to form if need additional documentation	No
Did this pharmacy have any uncorrected deficiencies from an inspection by another state or federal regulatory authority? If yes, indicate the repeat deficiencies. Attach to form if need additional documentation.	No
Has this pharmacy been inspected as part of the NABP Verfied Pharmacy Program? If so, note any uncorrected deficiences identified by NABP.	No
Has this pharmacy been inspected by any federal agency or another state? If so, please list inspecting agency and date, and any uncorrected deficiencies noted.	No

CHECKLIST NAME: Nonsterile Cmpd Lic Insp

Checklist Item	Status
Does the pharmacy dispense nonsterile compounded preparations pursuant to a prescription?	Yes
Are patient profiles complete and DUR performed for each prescription? View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.	Yes
Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?	Yes
Are nonsterile compounded prescriptions picked up at the pharmacy?	Yes
Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities? **Comment:** Homes via fedex	Yes
Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?	No
Does the pharmacy distribute nonsterile compounded preparations not pursuant to a prescription or labeled by the pharmacy with a patient name?	No
Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?	No
Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?	No
Does the pharmacy have a sales force that distributes samples containing active ingredients? List samples provided.	No
Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?	No
If so, does the pharmacy have central fill contracts or agreements with these pharmacies for patient specific preparations?	No

Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? Indicate which in Notes. **Comment:** capsules, liquids, creams	Yes
Does the pharmacy compound topicals (creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? Indicate which in Notes **Comment:** creams, ointments, inserts, suppositories, nasal sprays.	Yes
Does the pharmacy compound vitamin or nutritional supplements?	No
Does the pharmacy compound investigational drugs? If so, provide list.	No
Does the pharmacy make a copy of an approved commercial product? Indicate volume or percent compounded currently in note.	No
Products are verified as not available via FDA list and/or the manufacturer and documented?	No
FDA list is monitored (and manufacturer) and when item is taken off the list or becomes available, any remaining stock is quarantined for destruction and not dispensed or distributed? **Comment:** Not making any at this time.	Yes
Does the pharmacy perform compounding identified as simple? Indicate percentage of simple compounding in Notes 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. **Comment:** 20%	Yes
Does the pharmacy perform compounding identified as moderate? Indicate percentage of moderate compounding in Notes 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available. **Comment:** troches, suppositories, capsules	Yes
Does the pharmacy perform compounding identified as complex? Indicate percentage of complex compounding in Notes Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. **Comment:** hazardous HRT	Yes
Does the pharmacy perform compounding with hazardous drugs? Indicate percentage of hazardous nonsterile compounding in NotesNIOSH list of hazardous drugs including chemotherapy, hormones, etc. **Comment:** 30%, no chemo	Yes
Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>? **Comment:** effective 11/1/23	Yes
Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, hazardous drug compounding waste. Indicate how often the bin is emptied/collected and the vendor used. **Comment:** Stericycle	Yes

Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?	Yes
Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? Verify that personnel can access them and are familiar with the format.	Yes
Does the pharmacy compound using any controlled substances? Indicate percentage of controlled substance nonsterile compounding in Notes **Comment:** 10-15%	Yes
APIs: Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes
Does the pharmacy purchase APIs directly from the manufacturer? If not, indicate the source of APIs.	No
Does the pharmacy verify that the manufacturer of the API is an FDA-registered facility? How? If not, indicate how the pharmacy ensures quality. **Comment:** Known approved suppliers	Yes
Does the pharmacy use active ingredients that are not from an FDA facility? If so, indicate sources	No
Does the computer track on-hand quantities of APIs used for compounding?	Yes
Does the pharmacy perform any testing in-house (not sent to an outside lab)? If so, what tests are performed in house?	No
Does the pharmacy send samples to an outside lab to perform testing? If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.	Yes
Quality Assurance/Quality Improvement: Does the pharmacy continuous quality improvement program include nonsterile compounding measures? QREs related to the preparation of compounded products Personnel testing and validation Equipment calibration, testing and validation End product testing (such as: potency, particulates, consistency, etc.) Patient or prescriber reports or complaints regarding nonsterile compounded products.	Yes
Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes
Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?	Yes
Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?	N/A
Active Pharmaceutical Ingredients (APIs), bulk drug substances: All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3).On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Yes
Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products. NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound.	Yes
USP- or NF-grade substances used, if available	Yes
If compendial quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	N/A
APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies? Photograph and describe in notes below if found. Request copies of the invoices for products with questionable labels.	N/A
If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding **Comment:** No "vet use only" products compounded are for both humans and animals and no restrictive labeling seen.	Yes

All substances and components have a complete label including a batch control or lot number, and an expiration date.	Yes
For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. Note: purity and quality testing may be performed to extend.	Yes
All APIs and components received without an expiration date are labeled with the date they were received.	Yes
If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	N/A
Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Yes
Components from foreign sources that are derived from ruminant animals (cow, sheep, goat) have documentation that the component is in compliance with federal laws governing processing, use, and importation? That the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist. **Comment:** Thyroid porcine.	Yes
Where water is an ingredient, purified or distilled water is used. **Comment:** Reverse osmosis system.	Yes
Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.	N/A
There are no preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	N/A
When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	N/A
For animal compounding: The compounding meets the same standards as compounding for human patients.	Yes
The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	Yes
It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet. **Comment:** Pets only.	Yes
The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A
The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A
The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A
BUDs are assigned from the day of preparation.	Yes
BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.	Yes
BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).	N/A
BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.	N/A
BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.	Yes
Extended BUDs are supported by testing data. View documentation used, preparation must exactly match formulation upon which data was obtained.	Yes
The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	Yes
There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.	Yes
Only one preparation compounded at a time.	Yes
Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.	Yes

The compounding area is well lit.	Yes
The pharmacy performs hazardous non-sterile compounding a ventilated cabinet such as a BSC, CAI, or CACI. Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)	Yes
Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.	Yes
RECOMMENDED: Hood prefilters are checked and replaced regularly. **Comment:** monthly	Yes
If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.	Yes
Appropriate protective attire (gowns, gloves, masks, etc.) is available including appropriate PPE for hazardous drug compounding, if hazardous drugs are used.	Yes
There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.	Yes
There is adequate space to wash equipment and utensils including access to water for rinsing)(Purified water is recommended - not required)	Yes
The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.	Yes
Temperature in the compounding area is maintained to provide controlled room temperature storage of 20 to 25C (68 to 77F), or more restrictive if warranted by specific drug product storage requirements.	Yes
Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Yes
Excursion action plan in place including evaluating excursion effects on drug product integrity.	Yes
Temperature monitoring is also performed in drug storage areas (if separate from the compounding areas).	Yes
Humidity in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a ?dry place?, humidity is not to exceed 40%. Generally recommended range is 35-60%.	Yes
Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Yes
Excursion action plan in place including evaluating excursion effects on drug product integrity.	Yes
Humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).	Yes
The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.	Yes
All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.	Yes
All components and packaging containers and closures are properly rotated to use oldest first.	Yes
Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)	Yes
Trash is disposed of in a safe, sanitary, and timely manner including hazardous waste.	Yes
Recommended: Environmental testing is performed to detect contamination by drug residue in the pharmacy areas or areas served by the same ventilation system? Drug residue may cause cross contamination to other products and expose staff. Not required but is recommended if compounding with hazardous materials or known allergens such as penicillin, not using a hood, or the compounding room not segregated.	N/A
Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.	Yes
There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.	Yes
There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.	Yes
There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. Documentation includes operation and troubleshooting	Yes

The containers and closures selected meet USP standards (from container supplier).	Yes
Container selection determined by physical and chemical properties of the preparation.	Yes
Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.	Yes
Personnel don appropriate protective garb when performing compounding including hazardous compounding.	Yes
Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly	Yes
Procedures for in-process checks followed. These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage. Recommended: compounding accuracy checked by a person other than the compounder.	Yes
If there are any deviations from the master formulation record, these deviations are recorded.	Yes
There is a plan for cleaning. After each preparation, daily tasks, monthly tasks, etc.	Yes
Personnel are appropriately garbed for protection when cleaning. **Comment:** Technician had lots of hair exposed even while wearing cap.	No
Compounding employees are using appropriate techniques. Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment. Compounding MUST be observed, if compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the ?Denial of Authorization? form and mark item as "Non-Compliant".	Yes
The finished preparation is observed to appear as expected in the master formulation record and documented.	Yes
As appropriate, the final completed preparation assessed for weight, mixing, clarity, odor, color, consistency, pH, and strength and is documented.	Yes
There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.	Yes
Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics. **Comment:** No extended BUDs used.	N/A
If any failed tests or discrepancies are observed, there an investigation and appropriate corrective actions taken before dispensing to patient	N/A
If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.	N/A
There are appropriate control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. Validation of equipment and personnel performance documentation	Yes
Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.	Yes
Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).	Yes
Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Yes
Preparations are stored properly prior to dispensing based upon conditions upon which BUD was assigned.	Yes
Preparations are examined immediately after preparation AND again immediately prior to dispensing for any signs of instability.	Yes
Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?	Yes
Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?	Yes

Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy? **Comment:** Labeling and information provided to patients does not contain information on what product instability or contamination may look like.	No
Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk. **Comment:** No recalls have occurred since opening pharmacy.	Yes

There is documentation available showing employees performing non-sterile compounding are evaluated at least annually (including hazardous drug handling).	Yes
If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified. **Comment:** no relief personnel.3 RPhs	N/A
Number of personnel training files viewed: **Comment:** Several, specifically viewed Williams. All maintained in computer.	Yes
Appropriate equipment and utensils are available, clean, and in good working order. Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.	Yes
Scales, balances, or other equipment used for measurement is validated and calibrated at least annually. If scales are NOT validated and sealed by a state or local weights and measures agency, describe procedure used below in notes.	Yes
Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function. Hood filters are checked regularly and replaced when necessary.	Yes
All equipment is cleaned promptly after each use. Equipment and utensils washed using potable water with a soap or detergent, and rinsed. Recommended rinsed with purified water.	Yes
The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.	Yes
The pharmacy creates a master formulation record the first time before compounding a new preparation	Yes
Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.	Yes
The master formulation record contains: 1) Official or assigned name, strength, and dosage form 2) All necessary calculations 3) Description of all ingredients and their quantities 4) Compatibility and stability information including references (when available) 5) Equipment used for the preparation 6) Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors) 7) Container used and packaging requirements 8) Assigned BUD information 9) Labeling information including the name of and quantity or concentration of each active ingredient 10) Description of the finished preparation 11) Storage requirements 12) Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator)	Yes
The pharmacy creates a compounding record for each compound prepared	Yes
The compounding record includes: 1) Official or assigned name, strength and dosage of the preparation 2) Master Formulation Record reference 3) Sources, lot numbers, and expiration dates of all components 4) Total quantity or number of dosage units compounded 5) Person compounding the preparation 6) Person performing the quality control procedures 7) Person who approved the preparation 8) Date of compounding 9) Assigned internal identification number or prescription number 10) Description of the final preparation 11) Assigned BUD 12) Duplicate label 13) Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)? 14) Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate	Yes
The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.	Yes
Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.	Yes

5301013103APP23

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

VALIANT PHARMACY HOLDINGS, LLC
1274 ANNA J STEPP
YPSILANTI, MI 48197

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
PHARMACY LICENSE

VALIANT PHARMACY HOLDINGS, LLC
1274 ANNA J STEPP
YPSILANTI, MI 48197

LICENSE NO.
5301013103

EXPIRATION DATE
06/01/2025

23152110652

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

GRETCHEN WHITMER
GOVERNOR

ORLENE HAWKS
DIRECTOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

VERIFICATION OF LICENSURE
MICHIGAN BOARD OF PHARMACY

Eihab Z Swidan
8464 JACK PINE DR.
Ypsilanti, MI 48197

NAME: **VALIANT PHARMACY HOLDINGS, LLC**
ADDRESS: 1274 ANNA J STEPP
YPSILANTI, MI 48197

STATUS: Active

LICENSE TYPE: Pharmacy License

LICENSE NUMBER: 5301013103

ORIGINAL DATE: 06/01/2023
EXPIRATION DATE: 06/01/2025
SPECIALTY:
None

EXAM DATE	EXAM TYPE	EXAM RESULTS
	None	

OPEN FORMAL COMPLAINTS

No

DISCIPLINARY ACTION	START DATE	END DATE
None		

Brian DeBano, Division Director
Bureau of Professional Licensing
Licensing Division
(517) 241-0199

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FV2997128	05-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-17-2023

VALIANT PHARMACY HOLDINGS, LLC
1274 ANNA J STEPP DR
YPSILANTI, MI 48197

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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UNITED STATES DEPARTMENT OF JUSTICE
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WASHINGTON D.C. 20537

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VALIANT PHARMACY HOLDINGS, LLC
1274 ANNA J STEPP DR
YPSILANTI, MI 48197

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Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Valiant Pharmacy Holdings, LLC dba Valiant Compounding Pharmacy

Pharmacy/Wholesaler License # (if applicable) 5301013103

Physical Address 1274 Anna J Stepp Dr.

City Ypsilanti State MI Zip 48197

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 734-545-1117 Website www.Valiantrx.com

Licensing Company Email eswidan@Valiantrx.com

Section 2: Personal Information

First Eihab Middle Z. Last Swidan

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Jack Pine Dr.

City Ypsilanti State MI Zip 48197

Telephone [redacted] Email eswidan@Valiantrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Michigan College of Pharmacy		8/93 - 5/98	
Address	**City**	**State**	**Zip**
428 Church St.	Ann Arbor	MI	48109
Diploma/Degree obtained, if any			
Pharm D, Doctor of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Lincolin Consolidated		9/88 - 6/91	
Address	**City**	**State**	**Zip**
7425 Wills Rd.	Ypsilanti	MI	48197
Diploma/Degree obtained, if any			
Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/09 to present	[redacted] Jack Pine Dr.	Ypsilanti	MI	48197
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Valiant Compounding Pharmacy			12/22 to present	
Business Address		**City**	**State**	**Zip**
1274 Anna J. Stepp Dr.		Ypsilanti	MI	48197
Phone	**Title**		**Number of Employed Hours**	
734-545-1117	CEO		40 hours weekly	
Description of Duties	Manages day to day operations, oversees employees. helps pharmacists with thier duties when needed			

Business Name			From - To (MM/YY – MM/YY)	
Pharmacy Solutions			9/01 - 12/22	
Business Address		**City**	**State**	**Zip**
5204 Jackson Rd. Suite C		Ann Arbor	MI	48103
Phone	**Title**		**Number of Employed Hours**	
734-821-8000	COO		40 hours weekly	
Description of Duties	Manages day to day operations and administration worked closely with department head and supervisiors to support day to day activities of employees			

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Eihab Z. Swidan, certify that as the designated representative for Valiant Pharmacy Holdings, LLC, dba Valiant Compounding Pharmacy

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Eihab Z. Swidan
Print Name (First, Last)

Original Signature (~~electronic, copies or stamps~~ not accepted)

6/5/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Eihab Z. Swidan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/5/24

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Washtenaw

I, Eihab Z. Swidan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/5/24

Date

Subscribed and Sworn to before me this 5th day of June 2024

Christine Robertson

Notary Public Signature

CHRISTINE ROBERTSON
NOTARY PUBLIC, STATE OF MI
COUNTY OF LIVINGSTON
MY COMMISSION EXPIRES Sep 9, 2029
ACTING IN COUNTY OF Washtenaw

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Valiant Pharmacy Holding, LLC dba Valiant Compounding Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 5302029783

Physical Address 1274 Anna J. Stepp Dr.

City Ypsilanti State MI Zip 48197

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 734-545-1117 Website WWW.Valiantrx.com

Licensing Company Email eswidan@valiantrx.com

Section 2: Personal Information

First Ehab Middle Z. Last Swidan

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Tack Pine Dr.

City Ypsilanti State MI Zip 48197

Telephone [redacted] Email eswidan@valiantrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
University of Michigan College of Pharmacy	8/93 - 5/98

Address	City	State	Zip
428 Church St.	Ann Arbor	MI	48109

Diploma/Degree obtained, if any: Doctor of Pharmacy

School Name	From - To (MM/YY – MM/YY)
Lincoln Consolidated	9/88 - 6/91

Address	City	State	Zip
7425 WWRS Rd.	Ypsilanti	MI	48197

Diploma/Degree obtained, if any: Diploma

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/09 to present	[redacted] Jack Pine Dr.	Ypsilanti	MI	48197
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Valiant Compounding Pharmacy			From - To (MM/YY – MM/YY): 12/22 to present
Business Address: 1274 Anna J. Stepp Dr.	City: Ypsilanti	State: MI	Zip: 48197
Phone: 734-545-1117	Title: CEO		
Description of Duties: Manages day to day operations, oversees employees, helps pharmacists with thier duties when needed.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Eihab Z. Swidan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/5/24

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Washtenaw

I, Eihab Z. Swidan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/5/24

Date

Subscribed and Sworn to before me this 5th day of June, 2024

Christine Robertson

Notary Public Signature

CHRISTINE ROBERTSON
NOTARY PUBLIC, STATE OF MI
COUNTY OF LIVINGSTON
MY COMMISSION EXPIRES Sep 9, 2029
ACTING IN COUNTY OF Washtenaw

CHRISTINE ROBERTSON NOTARY PUBLIC LIVINGSTON COUNTY, MI

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Valiant Pharmacy Holdings, LLC dba Valiant Compounding Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 5302031765

Physical Address 1274 Anna J. Stepp Dr.

City Ypsilanti State MI Zip 48197

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 734-545-1117 Website www.valiantrx.com

Licensing Company Email hsmidi@valiantrx.com

Section 2: Personal Information

First Hussein Middle A Last Smidi

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Kess Dr

City Macomb State MI Zip 48044

Telephone [redacted] Email hsmidi@valiantrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Toledo		9/98 - 6/00	
Address	City	State	Zip
2801 Bancroft St.	Toledo	OH	43606
Diploma/Degree obtained, if any			
Masters of Business Administration			
School Name		From - To (MM/YY – MM/YY)	
University of Toledo		9/92 - 6/97	
Address	City	State	Zip
2801 Bancroft St.	Toledo	OH	43606
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmacy			
School Name		From - To (MM/YY – MM/YY)	
O.M.E.C		9/88 - 6/92	
Address	City	State	Zip
Bekaa Valley	Khiyara	Lebanon	
Diploma/Degree obtained, if any			
High School			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/04-Present	[redacted] Koss Dr.	Macomb	MI	48044
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Valiant Compounding Pharmacy			From - To (MM/YY – MM/YY): 12/22 to present
Business Address: 1274 Anna J. Stepp Dr.	City: Ypsilanti	State: MI	Zip: 48197
Phone: 734-545-1117	Title: Managing Partner		
Description of Duties: Manages resources, supervises staff to ensure quality of work. Ensures financial performance and profitability. Provides leadership to the team.			

Business Name: Memphis Drugs			From - To (MM/YY – MM/YY): 2/06 to present
Business Address: 80850 Main St.	City: Memphis	State: MI	Zip: 48041
Phone: 810-392-2424	Title: Owner		
Description of Duties: Oversees the ongoing operations of day to day business activities, fills in for pharmacists when needed			

Business Name: Armada Pharmacy			From - To (MM/YY – MM/YY): 1/09 to present
Business Address: 23032 E. Main Street	City: Armada	State: MI	Zip: 48005
Phone: 586-784-9222	Title: Owner		
Description of Duties: Oversees the ongoing operations of all departments, ensures general operations run smoothly.			

Business Name: Rx Solutions NWO			From - To (MM/YY – MM/YY): 1/23 to present
Business Address: 4895 Monroe St. Suite 200	City: Toledo	State: OH	Zip: 43623
Phone: 787-413-2938	Title: Owner		
Description of Duties: Oversees on going operations of all departments, ensures general operations run smoothly			

Business Name: Sunshine Pharmacy			From - To (MM/YY – MM/YY): 1/11 to 2/12
Business Address: 43600 Garfield Rd.	City: Clinton Twsp.	State: MI	Zip: 48038
Phone:	Title: Owner		
Description of Duties: Oversaw the ongoing operations of day to day business activities.			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hussein A. Smidi
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/5/24
Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Washtenaw

I, Hussein A. Smidi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/5/24
Date

Subscribed and Sworn to before me this 5th day of June 2024

Christine Robertson
Notary Public Signature

CHRISTINE ROBERTSON
NOTARY PUBLIC, STATE OF MI
COUNTY OF LIVINGSTON
MY COMMISSION EXPIRES Sep 9, 2029
ACTING IN COUNTY OF Washtenaw

CHRISTINE ROBERTSON NOTARY PUBLIC STATE OF MICHIGAN LIVINGSTON COUNTY

(Seal)

4DDD

RECEIVED
7/17/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist to Engage in the Practice of Pharmacy at a Site other than a Licensed Pharmacy

Rev (04/18/2023)

This application cannot be returned by fax or email.
We must have an original signature to process.

Section 1: Select the following that applies to you.
☐ I am employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 3, 5, 7)
☐ I am a pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution (If you marked this answer complete section 1, 2, 3, 5, 7)
☒ I am NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 4, 5, 6, 7)

Section 2: General Information

First: Christopher Middle: M. Last: Tyler

NV Pharmacist Registration #: 16752

Telephone: [redacted] Email: [redacted]

Section 3: Nevada Licensed Pharmacy as defined in NRS 639.012, or Nevada State Government Entity Information

Pharmacy/State Government Entity Name: _____

NV Pharmacy License # (if Pharmacy) or State Issued License # (if State Government Entity): _____

Address: _____

City: _____ State: _____ Zip: _____

Employer Contact Name: _____

Employer Contact Telephone: _____ Employer Contact email: _____

Section 4: Employer Information

Name or Identity of Employer or Business as registered with the Nevada Secretary of State chapter 76 of NRS:

Elevate Medical Group (Edwards),PLLC

Address: 2470 St. Rose Parkway Suite #308

City: Henderson State: NV Zip: 89074

Employer Contact Name: Johnathan Edwards

Employer Contact Telephone: [redacted] Employer Contact email: [redacted]

Section 5: Place where the Pharmacist will Engage in the Practice of Pharmacy (list all sites)

Name of Site (if applicable): Elevate Medical Group

Address: 2470 St. Rose Parkway Suite #308

City: Henderson State: NV Zip: 89074

Country/Territory/Province: U.S.A./ Nevada/ Clark County

Is this a medical, residential, or business site? ☒ Medical ☐ Residential ☒ Business

Days of the week and hours services will be provided at this site? M-F 8am-6pm

---

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

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Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

(Use and make copies of this page if necessary)

Section 6: NAC 639.403 A registered pharmacist who is NOT employed by or under contract with a pharmacy and who is NOT an employee of the State Government MUST complete this section

1. Provide a description of the services that you intend to provide at the site, to include only those services listed in Section 7 (A) of this application.

- Provide medication therapy managment services to clinic patients to optimize medication regimens,improve adherenace, and reduce adverse effects.
- Provide pre-appointment health screening (review current medications, health conditions, diet and lifestyle status to determine health risks).
- Provide patient education on medications, and explain medications, instructions,side effects, and precautions.
- Provide patient education on lifestyle modifcations and track treatment progress throughout treatment.
- Provide collaboration with medical team and offer drug related expertise to improve patient outcome

2. Provide the identification of the types of patients or other persons to whom you intend to provide services.

- The main types of patients will be patients coming to the clinic for treatment of weight management/obesity, patients coming to clinic for hormone replacement and patient coming to the clinic for I.V. hydration services to maintain optimal wellbeing and physical health.

3. Provide a description of all resources, both paper and electronic, that will be available to you in the course of providing the services.

- The pharmacist will have user access to the clinics Electronic Health records and patient profiles, including demographics, medical history, surgical history, lab history, medication history and chart notes from medical team.
- The pharmacist will have access to patient paper records as well, such as patient intake and informed consent forms.
-The pharmacist will have access to medical journals and other treatment guidlines through EHR system
- The pharmacist will have direct access to clinics medical director to discuss any clinical questions that may arise during the course of patient treatment.

4. Provide an explanation of the policy for users of the services when you are unavailable.

- If the pharmacist is unavailable there will be other clinical staff (registered nurses/medical director) that patients will be able to consult with and if nessary the pharmacist can be reached on his personal cell phone to discuss any urgent patient needs.

5. Provide an explanation of the policy regarding the confidentiality and security of the patient data that will be gathered, made, and maintained as part of the services which are provided, including without limitation, paper and electronic records.

- Any patient data that is collected will be stored snd safe gaurded in the clinics EHR system and the pharmacist will have his own secure login.

6. Provide a description of the business plan for the services provided.

-Elevate Medical Group is a private clinic , who's main focus is helping patients achieve optimal health before chronic disease takes is toll on individual patient health.The clinic's primary focus is weight loss/obesity management, hormone replacement, and I.V. hydration services. The clinics medical director Dr. Johanthan Edwards has long provided longevity and functional health expertise to countless patients. He and Dr. Tyler believe in the collaborative benefits of having a pharmacist in clinic to bring better understanding and education to patients when it comes to their medications and health conditions.

Section 7- Laws pertaining to engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy. Please read Section 7 in its entirety. By signing this application, you attest you have read and understood the components in this section.

A. NAC 639 - For all registered pharmacists engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy

1. While engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy, a registered pharmacist may perform only:
    a. The functions described in paragraphs (b), (c), (d) and (g) to (j), inclusive, of subsection 1 or NRS 639.0124, except for dispensing or administering drugs;
    b. The functions described in section 4 of LCB File No. R036.21, except for dispensing a self-administered hormonal contraceptive; and
    c. The administration of immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive.
2. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall:
    a. Provide written notice of the site of practice to the Executive Secretary in accordance with NAC 639.225 on this application; (NAC 639.225 states that a Nevada pharmacist, within 10 days after changing residence or place of practice, must give written notice of the change to the Board.)
    b. Ensure that the records of the registered pharmacist are made readily accessible to members of the Board and employees, agents and designees of the Board; and
    c. Comply with all applicable federal and state laws and regulations, including, without limitation:
        i. The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the regulations adopted pursuant thereto, and any other applicable federal or state law concerning the privacy of information regarding health care; and
        ii. Requirements relating to the maintenance or records.
3. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not maintain an inventory of drugs at that location.
4. A registered pharmacist shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy if he or she:
    a. Serves as a managing pharmacist; or
    b. Provides pharmaceutical services at:
        i. A facility for modified medical detoxification, as defined in NRS 449.00385;
        ii. An independent center for emergency medical care, as defined in NRS 449.013;
        iii. A facility for intermediate care, as defined in NRS 449.0038;
        iv. A facility for skilled nursing, as defined in NRS 449.0039; or
        v. A surgical center for ambulatory patients, as defined in NRS 449.019.

B. NAC 639 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is employed by or under contract with a pharmacy or who is an employee of the State Government may engage in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy unless he or she is provided with the same computerized system and access to data regarding a patient for whom a prescription has been submitted that is available to a registered pharmacist in the pharmacy. Such data must include, without limitation:

a. A legible copy of the prescription that is available as an electronic copy or a scanned image in the computerized system of the pharmacy or by facsimile machine; and
b. Any information that is available in the computerized system of the pharmacy that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.

C. NAC 639.403 - For a registered pharmacist who is NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity

For a registered pharmacist who is NOT employed by or under contract with a pharmacy or who is an employee of the State Government shall not engage in the practice of pharmacy at a site other than the site of a licensed pharmacy unless he or she obtains the approval of the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy. To request such approval, the registered pharmacist must submit this application. The application must be approved before a registered pharmacist may commence any practice.

D. NAC 639.4916 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution

1. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide the remote chart order processing services to the hospital or correctional institution that the pharmacy is required by NAC 639.4915 to provide must:
    a. Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the registered pharmacist must comply, including, without limitation, the provisions of pharmaceutical services, security, and confidentiality of patient records; and
    b. Be provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a registered pharmacist employe by the pharmacy located within the hospital or correctional institution, including, without limitation:
        i. The height, weight and age of the patient and any allergies that the patient may have;
        ii. The medical records regarding any medications prescribed to the patient;
        iii. The results of any relevant laboratory tests;
        iv. The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;
        v. Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;
        vi. A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and
        vii. Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.
2. Before a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution, the registered pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The registered pharmacist must, before approving a chart order to be filled, evaluate:
    a. The overutilization or underutilization of a medication;
    b. Therapeutic duplication;
    c. The appropriateness of the prescribed dosage and route of administration;
    d. The appropriateness of the directions for use of the medication;
    e. The appropriateness of the duration of the treatment with the prescribed medication;
    f. Any contraindication of the medication and a particular disease, ailment or allergy of the patient;
    g. Any contraindication or interactions between multiple medications prescribed for the patient; and
    h. The potential abuse or misuse of a medication.
3. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution shall comply with the requirements of Section 7 (A) to the same extent as a registered pharmacist engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy pursuant to the provisions in Section 7 (B) and Section 7 (C).
4. In an emergency, a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may render remote chart order processing services without being provided with all the information required by paragraph (b) of subsection 1 of Section 7 (D) if the registered pharmacist believes, in his or her professional judgement, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.
5. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may refuse to approve the filling of a chart order if, in the judgement of the registered pharmacist, the chart order is not safe or reasonable for the patient. A registered pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.
6. Each time that a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution

provides remote chart order processing services pursuant to this section, the registered pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:

a. The name or identifier of the registered pharmacist;
b. The date and time that the registered pharmacist provided the services and, if applicable, approved the filling of a chart order; and
c. The specific services provided by the registered pharmacist.

7. The managing pharmacist of a pharmacy located within a hospital or a correctional institution may limit the remote chart order processing services provided pursuant to this section (Section 7 (D)).

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Christopher Tyler

Print Name

Original Signature, no copies or stamps accepted

7/6/24

Date

Board Use Only	Date Received: 7/17/24 For applicants who marked box 1 or 2 in Section 1: Executive staff to review, scanned into applicant file. For applicants who marked box 3 in Section 1: Executive staff to review, place on consent agenda.

5

ANNUAL DISCIPLINE CASES Reporting Period: January 2024 – August 2024			
FINDING	**HARM**	**DISCIPLINE INDIVIDUAL**	**DISCIPLINE FACILITY**
SC engaged in unprofessional conduct by an APRN when she sold/dispensed dangerous drugs without having obtained a certificate of registration.	N/A	Fined $5,000; assessed $500 in recoverable attorney's fees and costs.	N/A
TH overrode a DUR alert signaling a drug-interaction with another prescription. The prescription was misfilled and provided to the incorrect patient. MW failed to provide counseling or properly counsel patient's mother.	N/A	TH and MW each fined $1,000; assessed $350 in recoverable attorney's fees and costs.	Fined $2,000; assessed $350 in recoverable attorney's fees and costs.
CVS, as pharmacy/pharmacy owner, is responsible for the dispensing errors of its employees where the patient was given clonazepam 0.5mg instead of ibuprofen and amoxicillin which resulted in patient harm.	Yes	N/A	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.
MO issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances while travelling out of country. MO participated in deceitful transactions and billed Medicaid for services that respondent did not provide.	N/A	Certificate of Registration No. CS10935 is revoked. MO cannot reapply for a period of ten years. Fined $2,500; assessed $1,754.68 in recoverable attorney's fees and costs.	N/A
PR assisted in unauthorized prescribing when she allowed her medical assistant to use her signature stamp for controlled substance prescriptions.	N/A	Fined $1,500; assessed $500 in recoverable attorney's fees and costs.	N/A
CVS, as pharmacy/pharmacy owner, is responsible for the dispensing errors of its employee who erroneously dispensed Estradoil 0.5mg and failed to counsel the patient which resulted in patient harm.	Yes	N/A	Fined $3,000.00; assessed $2,000.00 in recoverable attorney's fees and costs.

JC, as managing pharmacist, is responsible for the dispensing errors of employees that failed to dispense Doxycycline 50mg simultaneously with another prescription Metronidazole 250mg which were supposed to be taken as the prescribed course of treatment.	N/A	Respondent fined $1,000.00; assessed $500.00 in recoverable attorney's fees and costs	Fined $2,000; assessed $1,000 in recoverable attorney's fees and costs.
CD Rx failed to properly disclose that they had pending administrative actions in Alabama and Louisiana Boards of Pharmacy on their 2020 business renewal application.	N/A	N/A	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.
EA failed to comply with the citation and fine dated June 30, 2023, due to his failure to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. EA was sent an Order to Show Cause on November 29, 2023, which he failed to appear, and a default was made. Respondent's Certificate of Registration No. 19224 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A	Certificate of Registration No. 19224 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A
JI failed to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. JI was sent an Order to Show Cause on November 29, 2023, which she failed to appear, and a default was made.	N/A	Certificate of Registration No. 09672 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A

OE failed to comply with the citation and fine dated June 30, 2023, due to her failure to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. OE sent an Order to Show Cause on November 29, 2023, which she failed to appear, and a default was made.	N/A	Certificate of Registration No. 16558 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	
VV is responsible for providing preprinted prescription blanks to Kindred Outpatient Wound Care Hospital. VV erroneously entered the prescriber's name Dr. L.R. on the illegal preprinted prescription blank form and dispensed several prescriptions which included a misfill of six tubes of 30g Santyl Ointment rather than one 30g tube.	N/A	Certificate of Registration No. 18969 is placed on probation for a period of two years; public reprimand; fined $5,000 for the violations; assessed $1,000 in recoverable attorney's fees and costs.	
RR failed to make timely payments of the $500 fine and the $500 in attorney's fees and costs pursuant to the agreed upon Stipulation and Order filed September 6, 2023.	N/A	Certificate of Registration No. PT20827 is revoked and cannot petition for reinstatement for a period of one year.	N/A
KT authorized an employee to independently access, possess, store and administer dangerous drugs to patients without practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondent did not establish a bona fide therapeutic relationship. In addition, Respondent falsified patient information and issued false prescriptions to obtain compounded dangerous drugs for office use.	N/A	Certificate of Registration No. CS06260 is placed on probation for a period of one year; public reprimand; fined $2,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A

MS failed to timely renew his Certificate of Registration Nos. CS25265, CS12420, and CS15562 on October 31, 2018, where he issued 2,684 prescriptions of controlled substances to 484 patients in Nevada between November 1, 2018, and June 21, 2023, without a valid controlled substance registration and without accessing the Prescription Monitoring Program (PMP) to review the patient utilization report. Respondent MS applied for a new Certificate of Registration No. CS35699 on June 22, 2023, where he failed to comply with all the requirements for prescribing under Nevada controlled substance registration and failed to review a patient utilization report.	N/A	Certificate of Registration No. CS35699 is placed on probation for a period of two years; public reprimand; fined $16,000 for the violations; and assessed $2,500 in recoverable attorney's fees and costs.	N/A
AA prescribed electronic prescriptions for controlled substances after the Nevada Board of Pharmacy suspended his Certificate of Registration No. CS21324 due to the Nevada Board of Medical Examiners (NSBME) summarily suspending his medical license for violating his prior NSBME disciplinary orders.	N/A	Certificate of Registration No. CS21324 is revoked and cannot petition for reinstatement for a period of two years. Respondent fined $5,000 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A
MK failed to query a PMP report for any of his prescriptions since January 19, 2016, to June 13, 2021. During the time period of January 19, 2016, to April 17, 2023, Respondent queried only two individual patients which Respondent had over 8,000 filled controlled substance prescriptions for over 6,800 patients.	N/A	Certificate of Registration No. CS23600 is fined $6,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A

PO's Owner received a large shipment of drugs without the managing pharmacist's knowledge.	N/A	N/A	Pharmacy License No. PH04369 is suspended for a period of one year; however, the suspension is stayed. Respondent fined $5,000 for the violations; and assessed $2,000 in recoverable attorney's fees and costs.
CS procured dangerous drugs for Aesthetics MedSpa and allowed an unlicensed person to possess, store, and/or administer these dangerous drugs without any supervision or direction by a practitioner.	N/A	Certificate of Registration No. CS27884 fined $1,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A
DVH is responsible for its employee's unlawful diversion of controlled substances which included 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam.	N/A	N/A	Pharmacy License No. IB02134 fined $10,000 for the violations; assessed $1,000 in recoverable attorney's fees and costs; quarterly inspections at the pharmacy's expense; and must maintain a perpetual inventory of all controlled substances in stock in the pharmacy.
ES is responsible for its employee's unlawful diversion of controlled substances which included 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam. Respondent ES failed to maintain perpetual inventory of Schedule II controlled substances.	N/A	Certificate of Registration No. 19265 is suspended for a period of one year; however, the suspension is stayed. Respondent fined $2,500 for the violations; and assessed $500 in recoverable attorney's fees and costs.	N/A
MH is responsible for its employee's unlawful diversion of controlled substances which included 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam. MH failed to maintain perpetual inventory of Schedule II controlled substances.	N/A	Certificate of Registration No. 18203 is suspended for a period of one year; however, the suspension is stayed. Respondent fined $2,500 for the violations; and assessed $500 in recoverable attorney's fees and costs.	N/A

WP employees misfilled Metformin Hydrochloride ER 500mg tablets ASC, quantity 360, with two bottles of 100 tablets of Metformin Hydrochloride ER 500 MG AS tablets and one bottle of amlodipine besylate tablet, USP 5mg, quantity 500.	Yes	N/A	Pharmacy License No. PH02772 fined $1,000 for the violations; and assessed $750 in recoverable attorney's fees and costs.
CVS exceeded the Nevada pharmacist to pharmaceutical technician supervision ratio of one to three.	N/A	N/A	Pharmacy License No. PH01095 fined $20,000 for the violations; assessed $750 in recoverable attorney's fees and costs; and quarterly inspections for a period of one year at the pharmacy's expense.
EN exceeded the Nevada pharmacist to pharmaceutical technician supervision ratio of one to three.	N/A	Certificate of Registration No. 19578 fined $750 for the violations; and assessed $250 in recoverable attorney's fees and costs.	N/A
LC operated without an administrator and failed to notify the Board within three business days, and they continued to operate as a medical products provider for more than ten business days without an administrator approved by the Board.	N/A	N/A	License No. MP00012 fined $1,000 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.
LC operated without an administrator and failed to notify the Board within three business days, and they continued to operate as a medical products provider for more than ten business days without an administrator approved by the Board.	N/A	N/A	License No. MP00122 fined $5,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.

NT filled an oral solution amoxicillin prescription for a 16-month-old toddler. The prescription incorrectly called for a dose large enough to treat a 290-pound adult. Respondent recognized the error on the prescription and attempted to telephone the prescribing practitioner for clarification.	Yes	Certificate of Registration No. 23478 fined $1,000 for the violations; and assessed $500 in recoverable attorney's fees and costs.	N/A
WP conducted business as a pharmacy without having designated and/or employed a managing pharmacist for its pharmacy location between October 6, 2023, to November 17, 2023.	N/A	N/A	License No. PH02587 fined $2,000 for the violations; and assessed $500 in recoverable attorney's fees and costs.
NK was found guilty of making a false record of COVID-19 vaccinations reportedly administered to her former boyfriend.	N/A	Certificate of Registration No. 20034 is revoked, and she cannot petition for reinstatement for a period of two years. Respondent fined $10,000 for the violations; and assessed $8,406.29 in recoverable attorney's fees and costs.	N/A
HM wrote 690 controlled substance prescriptions between March 18, 2018, and January 12, 2022, without having a Nevada Controlled Substance Registration.	N/A	Certificate of Registration No. PR14531 is revoked and cannot petition for reinstatement for a period of one year. Respondent fined $10,000 for the violations; and assessed $544.55 in recoverable attorney's fees and costs.	N/A
KJ prescribed 93 controlled substance prescriptions without a valid Nevada certificate of registration to prescribe controlled substances.	N/A	Certificate of Registration No. DV00607 fined $600 for the violations.	N/A
RDC is responsible for the actions of an employee who filled an oral solution amoxicillin prescription for a 16-month-old toddler. The prescription incorrectly called	Yes	N/A	License No. PH01965 fined $1000 for the violations; and assessed $500 in recoverable attorney's fees and costs.

for a dose large enough to treat a 290-pound adult.			
CVS 08789 is responsible for the actions of an employee who incorrectly administered a dose of meningococcal vaccine to a six-year-old patient.	No	N/A	License No. PH01257 fined $1500 for the violations; and assessed $1000 in attorney's fees and costs.
OM incorrectly administered a dose of meningococcal vaccine to a six-year-old patient.	No	Certificate of Registration No. 23030 fined $1500 for the violations; assessed $1000 in attorney's fees and costs; and must complete ten additional continuing education courses on immunizations.	N/A
MS prescribed controlled substances and failed to maintain and actively use the prescription monitoring program (PMP) and perform queries on patients as required by Nevada Law.	No	Certificate of Registration No. CS21884 fined $5000 for the violations; assessed $1000 in attorney's fees and costs.	N/A
EW served as Medical Director for The Tox Shop where he allowed employees to have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.	No	Certificate of Registration No. CS32395 is placed on probation for a period of one year; fined $2500 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
RR was the only practitioner who held a certificate of registration to dispense dangerous drugs at Family Doctors of Green Valley (FDGV). Respondent Ramanathan would engage in overseas travel on several occasions and would allow other non-licensed practitioners at FDGV to sell and/or dispense dangerous drugs and controlled substances while using his credentials.	No	Certificate of Registration No. CS14526 fined $5000 for the violations; and assessed $1500 in attorney's fees and costs.	N/A

MM subject to discipline by the Nevada State Board of Medical Examiners for violations related to prescribing controlled substances to treat acute and chronic pain and subsequently surrendered his DEA Registration No. FM2307468 for cause.	No	Certificate of Registration Nos. CS18967 and PD00257 are forfeited; fined $2000 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
MC stole a large quantity of controlled substances. The stolen items included at least 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepram, meperidine, and midazolam.	N/A	Certificate of Registration No. PT14524 is revoked, and she cannot petition for reinstatement for a period of ten years; and assessed $1500 in attorney's fees and costs as a condition of reinstatement.	N/A
GM, a non-pharmacist owner, had possession of the pharmacy keys and entered the pharmacy when no registered pharmacist was on duty, all in violation of the Board's regulation.	N/A	GM fined $2000 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
BV misfilled a prescription of escitatopram oxalate 5mg and erroneously dispensed estradiot 0.5mg. In addition, Respondent Vaknin failed to counsel the patient. Respondent Vaknin did not appear for the May 29-30, 2024, hearing and a default was taken against her registration.	Yes	Certificate of Registration No. 19231 is suspended until October 31, 2025, and must appear before the Board if she plans to renew her registration for the next biennial renewal; fined $4000 for the violations; and assessed $1988.71 in attorney's fees and costs.	N/A
WA was convicted of eight felony counts of distribution of a controlled substance.	N/A	Certificate of Registration NO. CS08254 voluntarily surrendered his Certificate of Registration No. CS08254; and assessed $1878.65 in attorney's fees and costs.	N/A

KP was involved in alcohol impairment while performing his duties as a practitioner.	N/A	Respondent's Certificate of Registration No. CS10594 is revoked, and Respondent may not reapply for reinstatement for a period of two years; Respondent assessed $1614.48 in attorney's fees and costs.	N/A
HC unlawfully diverted controlled substances for his personal use.	N/A	Certificate of Registration No. PT28442 is revoked, and Respondent may not apply for reinstatement for a period of 10 years; Respondent assessed $1522.69 in attorney's fees and costs.	N/A
JS subject to discipline by the Nevada State Board of Medical Examiners for violations related to prescribing controlled substances to treat pain. In addition, he failed to disclose the disciplinary action to the Nevada Board of Pharmacy on his 2016 biennial renewal application.	N/A	Certificate of Registration No. CS07913 is suspended, but the suspension is stayed and is placed on probation for a period of one year; fined $2000 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
ASPC provided preprinted prescription blanks and is responsible for misfilled prescriptions	N/A	N/A	License No. PH03347 is fined $5000 for the violations; and assessed $1000 in attorney's fees and costs.
KF, as managing pharmacist, is responsible recordkeeping violations related to vaccine administration.	N/A	Certificate of Registration No. 19635 is fined $500 for the violations.	N/A
EK issued prescriptions for compounded semiglutide under the names of her staff to Meta Pharmacy for administration by injection to multiple patients.	N/A	Certificate of Registration No. CS21522 is placed on probation for a period of one year; fined $2500 for the violations; assessed $1000 in attorney's fees and costs; and subject to quarterly inspections no more than $500 for a period of one year at the respondent's expense.	N/A

SB was disciplined for prescribing controlled substances without a valid registration and petitioned The Board to vacate the default Order and requested a re-hearing.	N/A	Certificate of Registration No. CS23773 request was denied.	N/A
JF at his place of practice called Century Wellness Center failed to properly label, segregate and/or dispose of adulterated and/or expired drugs, including multi-dose containers. In addition, Respondent Forsythe possessed in his inventory Veterinary 0.9% Sodium Chloride labeled “For Veterinary Use Only”.	N/A	Certificate of Registration No. CS05385 accept the Order as public reprimand regarding his duties and responsibilities as a practitioner when maintaining inventory of dangerous drugs; submit to a timely Board inspection at his practice; fined $5000 for the violations; and assessed $2384.08 in attorney’s fees and costs.	N/A
KB failed to query patient J.J.’s patient utilization report in the PMP database prior to issuing 22 separate controlled substance prescriptions. In addition, Respondent Burgner failed to query and review for accuracy her MyRx prescriber activity report at least once every six months from December 10, 2015, to June 23, 2022, as required by Nevada Law.	N/A	Certificate of Registration No. CS15148 fined $2,000 for the violations; and assessed $500 in attorney’s fees and costs.	N/A
RG failed to query patient J.J.’s patient utilization report in the PMP database prior to issuing 2 separate controlled substance prescriptions. In addition, Respondent Gonzalez failed to query and review for accuracy her MyRx prescriber activity report at least once every six months from January 29, 2018, to April 7, 2022, as required by Nevada Law.	N/A	Certificate of Registration No. CS11387 fined $2,000 for the violations; and assessed $500 in attorney’s fees and costs.	N/A

CVS is responsible for the acts of its employees who made an error in prescription that resulted in a negative outcome to the patient.	Yes	N/A	Pharmacy License No. PH02471 fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs.
AJ is responsible for an error in a prescription that resulted in a negative outcome to the patient.	Yes	Certificate of Registration No. 23280 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
NA, as verifying pharmacist, Respondent Aguas failed to review the actual physical contents of the prescription and is responsible for an error in the prescription.	Yes	Certificate of Registration No. 14977 fined $500 for the violations.	N/A
CVS, as pharmacy owner, CVS Pharmacy #8806 is responsible for the acts of its employees who made an error in prescription.	Yes	N/A	Pharmacy License No. PH100640 fined $5,000 for the violations; and assessed $4,787.82 in attorney's fees and costs.
MV did not conduct a MyRx review for all prescriptions Respondent has written for part of the calendar years 2017, 2019, and 2021. Respondent only queried nine times between January 1, 2018, to September 18, 2023, where he wrote at least 890 prescriptions for at least 650 unique patients	No	Certificate of Registration No. CS15506 shall accept this as a public reprimand; must comply with all PMP related laws and regulations; fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
CVS is responsible for the acts of an employee-pharmacist who failed to review patient M.C.'s record prior to counseling or reviewed the patient's profile in a manner that was inadequate to provide the patient proper counseling.	No	N/A	Pharmacy License No. PH01336 is fined $2,000 for the violations; and assessed $500 in attorney's fees and costs.
DM failed to review patient M.C.'s record prior to counseling or reviewed the patient's profile in a manner that was inadequate to provide the patient proper counseling.	No	Certificate of Registration No. 14845 is fined $1,000 for the violations; assessed $500 in attorney's fees and costs; and shall complete four additional continuing education credits on the topic of counseling.	N/A

NK was found guilty of making a false record of COVID-19 vaccinations reportedly administered to her former boyfriend and was disciplined by the Board at the April 17-18, 2024, Board Meeting. Thereafter, NS petitioned the Board for reconsideration of the discipline imposed and appeared at the July 17, 2024, Board Meeting. The Board amended the discipline imposed against NS.	No	Certificate of Registration No. 20034 is revoked; however, the revocation is stayed and Respondent is placed on probation for a period of five years; fined $5,000 for the violations; assessed $8,406.29 in attorney's fees and costs; as a condition of probation, Respondent's authority to engage in the practice of pharmacy is suspended for a period of one year from April 18, 2024; and Respondent must complete a 22-hour "Ethics and Professionalism" bootcamp course within 120 days of the Order.	N/A

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 19-012-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent pre-signed controlled substance prescriptions that were issued to patients by his staff while he was engaged in overseas travel. Respondent traveled outside of the United States on the following dates: July 14, 2016 – July 25, 2016; February 25, 2017 – March 11, 2017; September 27, 2017 – October 2, 2017; December 22, 2017 – December 28, 2017; and November 9, 2018 – November 30, 2018. Prescriber records and prescriptions document one-hundred and twenty-six (126) controlled substance prescriptions authorized by Respondent during these periods.

3. Respondent caused other practitioners who treated his patients to use his National Provider Identifier (NPI) while he was outside of the country to falsely bill Medicaid and other

commercial health insurance plans for services that Respondent did not personally provide, and received reimbursement for those services.

APPLICABLE LAW

4. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR §§ 1306.03-1306.05; NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.2355.

5. Falsifying a prescription for a controlled substance and the possession of signed prescription blanks are felony offenses. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(f), (h) and (i).

6. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

7. Medicaid fraud is a felony offense. 18 U.S.C. § 1347; 42 U.S.C.A. § 1320a-7b; NRS 422.540(1).

8. Insurance fraud is a felony offense. NRS 686A.2815; NRS 686A.291.

9. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

10. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of Federal Controlled Substances Act – Issuing Fraudulent Controlled Substance Prescriptions

14. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a) and/or 21 CFR § 1306.05(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Law – Issuing Fraudulent Controlled Substance Prescriptions

15. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f), (h) and (i), NRS 453.381(1), NRS

453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2355, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE

Violations of Federal and State Law – Medicaid Fraud/Insurance Fraud

16. By falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 18 U.S.C. § 1347, 42 U.S.C.A. § 1320a-7b, NRS 422.540(1), NRS 686A.2815 and/or NRS 686A.291, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

COUNT FOUR

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

17. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FIVE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

18. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3

herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT SIX

Commission of Acts that Render Registration Inconsistent with the Public Interest

19. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**CASE NO. 19-012-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**CASE NO. 19-012-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

FESTUS EBONKA, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Festus Ebonka, APRN
[redacted] E. Charleston Blvd
Las Vegas, NV 89104

Festus Ebonka, APRN
[redacted] Leadbrick St.
Las Vegas, NV 89143

SHIRLEY HUNTING
BOARD COORDINATOR

FILED
FEB 21 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. **FESTUS EBONKA, APRN,** Certificate of Registration No. CS23430 Respondent.	**Case No. 19-012-CS-S**

ANSWER AND NOTICE OF DEFENSE

Respondent, **FESTUS EBONKA, APRN,** by and through counsel, LIBORIUS AGWARA, ESQ., of the Law Offices of Libo Agwara, Ltd., hereby files his Answer and Notice of Defense to THE NEVADA STATE BOARD OF PHARMACY'S ("Board") Complaint and states as follows:

1. Answering Paragraphs 1 and 10, Respondent admits the allegations contained therein.

2. Answering Paragraphs 2, 3. 14, 15, 16, 17, 18 and 19, Respondent denies the allegations contained therein.

3. Answering Paragraphs 4, 5, 6, 7, 8, 9, 10, 11, 12 and 13, Respondent states that he is without sufficient knowledge as to the truth or falsity of the allegations contained therein, and as such denies them.

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LAW OFFICES OF LIBO AGWARA, LTD.
2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
702-385-4800 Phone

WHEREFORE, Respondent, respectfully requests that the Board find that he did not violate the Control Substance Act. Respondent further requests such other and additional relief as the Board may deem just and proper under the circumstances.

Dated this 21st day of February 2024.

LAW OFFICES OF LIBO AGWARA, LTD

LIBORIUS AGWARA, ESQ.
Nevada Bar No.: 7576
2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
Tel: (702) 385-4800 Phone
Libolaw@yahoo.com
Attorney for Respondent

LAW OFFICES OF LIBO AGWARA, LTD.
2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
702-385-4800 Phone

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. SMITH'S PHARMACY #350, Pharmacy License No. PH00758, and LOLITA SIMON CAOILE, RPH, Certificate of Registration No. 12687, Respondents.	CASE NOS. 19-247-PH-S 19-247-RPH-S NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Lolita Simon Caoile, RPh (Caoile), Certificate of Registration No. 12687, was a pharmacist registered with the Board, and Respondent Smith's Pharmacy #350, Pharmacy License No. PH00758, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Caoile was employed as managing pharmacist by Smith's Pharmacy #350 and Kalai was employed by Smith's Pharmacy #350, located at 4600 East Sunset Road in Henderson, Nevada, at the time of the events alleged herein.

3. On or about July 16, 2019, pharmaceutical technician Mary Kay Kalai, PT (Kalai), Certificate of Registration No. PT02753, an employee of Smith's Pharmacy #350, discarded approximately 58,000 prescription records in a trash compactor in violation of Smith's

company policies for secure records destruction. Kalai was subsequently terminated from employment for her actions.

APPLICABLE LAW

4. Prescription records constitute Protected Health Information (PHI) as defined in 45 C.F.R. § 160.103, protected from unauthorized disclosure under the Health Insurance Portability and Accountability Act of 1996. 45 C.F.R. Part 160 and Part 164, Subparts A and E (HIPPA Privacy Rule). The HIPPA Privacy Rule requires covered entities to develop and implement policies and procedures to reasonably safeguard PHI during the destruction process.

5. Prescription records are also confidential and protected from unauthorized disclosure under NRS 639.238, and must be destroyed in a secure manner consistent with NRS 603A.200.

6. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

7. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

8. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

9. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

10. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the

license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

COUNT ONE

Violation of Federal Law

(Respondents Caoile and Smith's Pharmacy #350)

11. Kalai discarded prescription records in violation of the HIPPA Privacy Rule. As the managing pharmacist of Smith's Pharmacy #350 at the time of the violations, Caoile is responsible for those violations and subject to discipline pursuant to NRS 639.210(11) and (15), NRS 639.220(1) and/or NAC 639.702.

12. As the pharmacy/pharmacy owner at which the violations of federal law occurred, Smith's Pharmacy #350 is responsible for those violations, including all errors and omissions of Kalai and/or Caoile, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

COUNT TWO

Violation of State Law

(Respondents Caoile and Smith's Pharmacy #350)

13. Kalai discarded prescription records in violation of NRS 639.238 and NRS 603A.200. As the managing pharmacist of Smith's Pharmacy #350 at the time of the violations, Caoile is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

14. As the pharmacy/pharmacy owner at which the violations of state law occurred, Smith's Pharmacy #350 is responsible for those violations, including all errors and omissions of Kalai and/or Caoile, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

15. As the managing pharmacist of Smith's Pharmacy #350 at the time the violations alleged herein occurred, Caoile has performed her duties as the holder of a Nevada pharmacist registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #350,** **Pharmacy License No. PH00758,** **Respondent.**	**CASE NO. 19-247-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #350,** **Pharmacy License No. PH00758,** **Respondent.**	**CASE NO. 19-247-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR SMITH'S PHARMACY #350

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Lolita Simon Caoile, RPH
[redacted] Kirkland Ranch CT
Las Vegas, NV 89139

Smith's Pharmacy #350
4600 E. Sunset RD
Henderson, NV 89014

SHIRLEY HUNTING
BOARD COORDINATOR

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FILED
JAN 2 5 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. SMITH'S PHARMACY #350, Pharmacy License No. PH00758, and LOLITA SIMON CAOILE, RPH, Certificate of Registration No. 12687, Respondents.	CASE NOS. 19-247-PH-S 19-247-RPH-S NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Lolita Simon Caoile, RPh (Caoile), Certificate of Registration No. 12687, was a pharmacist registered with the Board, and Respondent Smith's Pharmacy #350, Pharmacy License No. PH00758, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Caoile was employed as managing pharmacist by Smith's Pharmacy #350 and Kalai was employed by Smith's Pharmacy #350, located at 4600 East Sunset Road in Henderson, Nevada, at the time of the events alleged herein.

3. On or about July 16, 2019, pharmaceutical technician Mary Kay Kalai, PT (Kalai), Certificate of Registration No. PT02753, an employee of Smith's Pharmacy #350, discarded approximately 58,000 prescription records in a trash compactor in violation of Smith's

company policies for secure records destruction. Kalai was subsequently terminated from employment for her actions.

APPLICABLE LAW

4. Prescription records constitute Protected Health Information (PHI) as defined in 45 C.F.R. § 160.103, protected from unauthorized disclosure under the Health Insurance Portability and Accountability Act of 1996. 45 C.F.R. Part 160 and Part 164, Subparts A and E (HIPPA Privacy Rule). The HIPPA Privacy Rule requires covered entities to develop and implement policies and procedures to reasonably safeguard PHI during the destruction process.

5. Prescription records are also confidential and protected from unauthorized disclosure under NRS 639.238, and must be destroyed in a secure manner consistent with NRS 603A.200.

6. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

7. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

8. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

9. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

10. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the

license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

COUNT ONE

Violation of Federal Law

(Respondents Caoile and Smith's Pharmacy #350)

11. Kalai discarded prescription records in violation of the HIPPA Privacy Rule. As the managing pharmacist of Smith's Pharmacy #350 at the time of the violations, Caoile is responsible for those violations and subject to discipline pursuant to NRS 639.210(11) and (15), NRS 639.220(1) and/or NAC 639.702.

12. As the pharmacy/pharmacy owner at which the violations of federal law occurred, Smith's Pharmacy #350 is responsible for those violations, including all errors and omissions of Kalai and/or Caoile, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

COUNT TWO

Violation of State Law

(Respondents Caoile and Smith's Pharmacy #350)

13. Kalai discarded prescription records in violation of NRS 639.238 and NRS 603A.200. As the managing pharmacist of Smith's Pharmacy #350 at the time of the violations, Caoile is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

14. As the pharmacy/pharmacy owner at which the violations of state law occurred, Smith's Pharmacy #350 is responsible for those violations, including all errors and omissions of Kalai and/or Caoile, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

15. As the managing pharmacist of Smith's Pharmacy #350 at the time the violations alleged herein occurred, Caoile has performed her duties as the holder of a Nevada pharmacist registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 25th day of JANUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LOLITA SIMON CAOILE, RPH,** **Certificate of Registration No. 12687,** **Respondent.**	**CASE NO. 19-247-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LOLITA SIMON CAOILE, RPH,** **Certificate of Registration No. 12687,** **Respondent.**	**CASE NO. 19-247-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

LOLITA SIMON CAOILE, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Lolita Simon Caoile, RPH
[redacted] Kirkland Ranch CT
Las Vegas, NV 89139

Smith's Pharmacy #350
4600 E. Sunset RD
Henderson, NV 89014

SHIRLEY HUNTING
BOARD COORDINATOR

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

WALGREENS PHARMACY #05479,
Pharmacy License No. PH01938,

WALGREENS PHARMACY #02445,
Pharmacy License No. PH01964,

GRACE OPULENCIA, RPh.,
Pharmacist Registration No. 15190,

Respondent.

Case Nos. 21-169-PH-S
21-169-PH-O
21-169-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #05479 ("Walgreens #05479"), because at the time of the events alleged herein, Respondent Walgreens #05479 held Pharmacy License No. PH01938, issued by the Board, pursuant to NRS 639.230, on May 20, 2005, which authorized Respondent Walgreens #05479 to operate a pharmacy within the State of Nevada.

2. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #02445 ("Walgreens #02445"), because at the time of the events alleged herein, Respondent Walgreens #002445 held Pharmacy License No. PH01964, issued by the Board, pursuant to NRS 639.230, on September 9, 2004, which authorized Respondent Walgreens #02445 to operate a pharmacy which dispenses into the State of Nevada.

3. The Board has personal jurisdiction over Respondent Grace Opulencia, RPh. ("Opulencia"), because at the time of the events alleged herein, Respondent Opulencia held

Certificate of Registration No. 15190, issued by the Board, pursuant to NRS 639.127, on October 6, 2000, which authorized Respondent Opulencia to practice pharmacy in the State of Nevada.

4. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Opulencia was engaged in the practice of pharmacy at the pharmacy operated by Respondent Walgreens #05479 in the State of Nevada and Walgreens #02445 was operating a pharmacy which engaged in the practice of pharmacy into the State of Nevada.

PRIOR DISCIPLINE
(Respondent Opulencia)

5. On or about February 7, 2022, Respondent Opulencia was mailed a $500.00 Citation and Fine in Case No. 19-119-RPH-S for a medication misfill of Adderall XR capsules, 25mg wherein RX# 2969633 was short six capsules. Respondent Opulencia timely paid the $500.00 fine.

(Respondent Walgreens #02445)

6. In or about January of 2016, Respondent Walgreens #02445 a.k.a Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, entered into a Stipulation and Order in Case No. 15-028-RPH-S. In the Stipulation, Respondent Walgreens #02445 admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employee, who did not hold a Nevada pharmacist registration, had incorrectly verified a RX #3094107-3922, a prescription written for Zoloft 200mg as simvastatin 20 mg tablets (generic Zocor). Respondent Walgreens #02445 paid a fine of $1,000.00 and attorney's fees and costs of $495.00.

7. On or about April 10, 2019, Respondent Walgreens #02445, Certificate of Registration No. PH01964, entered into a Stipulation and Order Case No. 17-086-S. In the Stipulation, Respondent Walgreens admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employees who did not hold Nevada pharmacist registrations, had on three

separate occasions, overrode Drug Utilization Review ("DUR") warnings during the automatic refill data review of RX #1465131-04579. RX #1465131-04579 was written for Rophinirole 2mg, a treatment for restless leg syndrome, and incorrectly verified as Risperidone 2mg, an antipsychotic. Respondent Walgreens #02445 paid a fine of $2,000.00 and attorney's fees and costs of $1,000.00.

FACTUAL ALLEGATIONS

8. On or about October 14, 2021, the Board received a patient complaint indicating that the patient had incorrectly received preservative free single dose Methotrexate instead of the multidose Methotrexate containing a preservative.

9. Respondent Walgreens #05479 operated a pharmacy at 385 E. Silverado Ranch Blvd., Las Vegas, Nevada 89183 at the time of the events alleged herein.

10. Respondent Opulencia, RPh., was employed as a staff pharmacist at Walgreens #05479 at the time of the events alleged herein.

RX# 1930061-2

11. On or about August 2, 2021, Dana Shepherd, P.A. issued a prescription for "Methotrexate 50mg/2ml injection solution," with directions stating "0.5 milliliter inject subcutaneously one time weekly," and "#1 Bottle(s), 30-day, Refills: 2." The prescription was electronically transmitted to Respondent Walgreens #05479 and designated as RX# 1930061-2.

12. On or about August 3, 2021, pharmaceutical technician H.X. Jaghanan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the data entry for RX# 1930061-2. The data entry performed by H.X. Jaghanan identified prescription at "Methotrexate 25mg/ml PF SI."

13. Pharmaceutical technician H.X. Jaghanan is not licensed to practice pharmacy in the State of Nevada.

14. On or about August 23, 2021, pharmacist Julie Wan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the "Pat/Pbr rev" and "Data Product Review" for RX# 1930061-2.

15. Pharmacist Julie Wan is not licensed to practice pharmacy in the State of Nevada.

16. On or about August 23, 2021, pharmacist D. Pham, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, overrode 5 DURs for RX# 1930061-2.

17. Pharmacist D. Pham is not licensed to practice pharmacy in the State of Nevada.

18. On or about August 23, 2021, pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, who was located at Walgreens #05479, filled RX# 1930061-2.

19. On or about August 24, 2021, Respondent Opulencia performed the final verification and incorrectly verified RX# 1930061-2 as preservative free.

20. On or about August 26, 2021, RX# 1930061-2 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-2.

RX# 1930061-5 - REFILL

21. On or about September 28, 2021, Respondent Opulencia performed the final verification on a refill of RX# 1930061 and incorrectly verified the prescription as preservative free.

22. On or about September 28, 2021, RX# 1930061-5 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-5.

APPLICABLE LAW

23. A pharmacist, pharmacist intern, or dispensing practitioner shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation: (a) overutilization of the drug and drug

misuse; (b) underutilization of the drug; (c) therapeutic duplications, contradictions, and any warning labels or other information included with the drug; (d) interactions between the drug and any (i) other drugs which the patient is taking or has recently taken, (ii) diseases which the patient has, including any stages of the disease, and (iii) allergies that the patient may have; and (e) incorrect dosage or duration of treatment. NAC 639.707(4).

24. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder fails to strictly follow the instructions of a practitioner when filling, refilling, labeling, and dispensing a prescription. NAC 639.945(1)(d)

25. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder performed his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

26. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(12) upon the finding that the holder, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

27. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(15) upon the finding that the holder, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of NRS Chapter 639 or

other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision.

28. Each pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

29. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

30. If a pharmaceutical technician performs one of more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription, including but not limited to, verifying: (a) the selection and strength of the drug; the dosage form; and the labeling of the prescription. NAC 639.252(2).

31. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

32. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

33. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

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COUNT ONE

Unprofessional Conduct- Incompetent, Unskillful, or Negligent Conduct
(Respondent Opulencia)

34. Respondent Opulencia's failure to accurately verify the prescription dosage and duration in strict conformance with the instructions of prescribing practitioner prior to dispensing dispense RX# 1930061-2 and RX# 1930061-5 violated NAC 639.707(4)(e) and constituted unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest pursuant to NAC 639.945(1)(d) and/or (i). Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.210(12) and/or NRS 639.255(3).

35. Respondent Opulencia, as the managing pharmacist of Walgreens #05479 at the time of the violations alleged herein, is responsible, pursuant to NRS 639.220(1), for the misfills of RX# 1930061-2 and RX# 1930061-5, including pursuant to NAC 639.252(2) and NAC 639.702, if the misfills were attributable to the unprofessional conduct, including incorrect prescription data entry by pharmaceutical technician J.N. Zuniga, or any of the other pharmacy employee of Walgreens #05479 under the supervision of Respondent Opulencia. Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #05479)

36. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #05479, including Respondent Opulencia, or pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, Walgreens #05479 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #05479 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

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COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #02445)

37. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #02445, including pharmaceutical technician H.X. Jaghanan, pharmacist Julie Wan, or pharmacist D. Pham, Walgreens #02445 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #02445 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 6th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TwynBC@Pharmacy.nv.gov and p.keegan@harrypay.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of December 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR
Walgreens Pharmacy #05479

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of December, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Walgreens Pharmacy #05479
385 E Silverado Ranch Blvd.
Las Vegas, NV 89183

Walgreens Pharmacy #02445
8337 S Park Circle
Orlando, FL 32819

William Stilling, Esq.
222 South Main St., Suite 500
Salt Lake City, UT 84101

Grace Opulencia, RPH
[redacted] Tamarus St.
Las Vegas, NV 89123

Grace Opulencia, RPH
[redacted] E Silverado Ranch Blvd.
Las Vegas, NV 89183

Darlene Nases
DARLENE NASES

5E

FILED
DEC - 8 2023
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

WALGREENS PHARMACY #05479,
Pharmacy License No. PH01938,

WALGREENS PHARMACY #02445,
Pharmacy License No. PH01964,

GRACE OPULENCIA, RPh.,
Pharmacist Registration No. 15190,

Respondent.

Case Nos. 21-169-PH-S
21-169-PH-O
21-169-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #05479 ("Walgreens #05479"), because at the time of the events alleged herein, Respondent Walgreens #05479 held Pharmacy License No. PH01938, issued by the Board, pursuant to NRS 639.230, on May 20, 2005, which authorized Respondent Walgreens #05479 to operate a pharmacy within the State of Nevada.

2. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #02445 ("Walgreens #02445"), because at the time of the events alleged herein, Respondent Walgreens #002445 held Pharmacy License No. PH01964, issued by the Board, pursuant to NRS 639.230, on September 9, 2004, which authorized Respondent Walgreens #02445 to operate a pharmacy which dispenses into the State of Nevada.

3. The Board has personal jurisdiction over Respondent Grace Opulencia, RPh. ("Opulencia"), because at the time of the events alleged herein, Respondent Opulencia held

Certificate of Registration No. 15190, issued by the Board, pursuant to NRS 639.127, on October 6, 2000, which authorized Respondent Opulencia to practice pharmacy in the State of Nevada.

4. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Opulencia was engaged in the practice of pharmacy at the pharmacy operated by Respondent Walgreens #05479 in the State of Nevada and Walgreens #02445 was operating a pharmacy which engaged in the practice of pharmacy into the State of Nevada.

PRIOR DISCIPLINE
(Respondent Opulencia)

5. On or about February 7, 2022, Respondent Opulencia was mailed a $500.00 Citation and Fine in Case No. 19-119-RPH-S for a medication misfill of Adderall XR capsules, 25mg wherein RX# 2969633 was short six capsules. Respondent Opulencia timely paid the $500.00 fine.

(Respondent Walgreens #02445)

6. In or about January of 2016, Respondent Walgreens #02445 a.k.a Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, entered into a Stipulation and Order in Case No. 15-028-RPH-S. In the Stipulation, Respondent Walgreens #02445 admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employee, who did not hold a Nevada pharmacist registration, had incorrectly verified a RX #3094107-3922, a prescription written for Zoloft 200mg as simvastatin 20 mg tablets (generic Zocor). Respondent Walgreens #02445 paid a fine of $1,000.00 and attorney's fees and costs of $495.00.

7. On or about April 10, 2019, Respondent Walgreens #02445, Certificate of Registration No. PH01964, entered into a Stipulation and Order Case No. 17-086-S. In the Stipulation, Respondent Walgreens admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employees who did not hold Nevada pharmacist registrations, had on three

separate occasions, overrode Drug Utilization Review ("DUR") warnings during the automatic refill data review of RX #1465131-04579. RX #1465131-04579 was written for Rophinirole 2mg, a treatment for restless leg syndrome, and incorrectly verified as Risperidone 2mg, an antipsychotic. Respondent Walgreens #02445 paid a fine of $2,000.00 and attorney's fees and costs of $1,000.00.

FACTUAL ALLEGATIONS

8. On or about October 14, 2021, the Board received a patient complaint indicating that the patient had incorrectly received preservative free single dose Methotrexate instead of the multidose Methotrexate containing a preservative.

9. Respondent Walgreens #05479 operated a pharmacy at 385 E. Silverado Ranch Blvd., Las Vegas, Nevada 89183 at the time of the events alleged herein.

10. Respondent Opulencia, RPh., was employed as a staff pharmacist at Walgreens #05479 at the time of the events alleged herein.

RX# 1930061-2

11. On or about August 2, 2021, Dana Shepherd, P.A. issued a prescription for "Methotrexate 50mg/2ml injection solution," with directions stating "0.5 milliliter inject subcutaneously one time weekly," and "#1 Bottle(s), 30-day, Refills: 2." The prescription was electronically transmitted to Respondent Walgreens #05479 and designated as RX# 1930061-2.

12. On or about August 3, 2021, pharmaceutical technician H.X. Jaghanan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the data entry for RX# 1930061-2. The data entry performed by H.X. Jaghanan identified prescription at "Methotrexate 25mg/ml PF SI."

13. Pharmaceutical technician H.X. Jaghanan is not licensed to practice pharmacy in the State of Nevada.

14. On or about August 23, 2021, pharmacist Julie Wan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the "Pat/Pbr rev" and "Data Product Review" for RX# 1930061-2.

15. Pharmacist Julie Wan is not licensed to practice pharmacy in the State of Nevada.

16. On or about August 23, 2021, pharmacist D. Pham, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, overrode 5 DURs for RX# 1930061-2.

17. Pharmacist D. Pham is not licensed to practice pharmacy in the State of Nevada.

18. On or about August 23, 2021, pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, who was located at Walgreens #05479, filled RX# 1930061-2.

19. On or about August 24, 2021, Respondent Opulencia performed the final verification and incorrectly verified RX# 1930061-2 as preservative free.

20. On or about August 26, 2021, RX# 1930061-2 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-2.

RX# 1930061-5 - REFILL

21. On or about September 28, 2021, Respondent Opulencia performed the final verification on a refill of RX# 1930061 and incorrectly verified the prescription as preservative free.

22. On or about September 28, 2021, RX# 1930061-5 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-5.

APPLICABLE LAW

23. A pharmacist, pharmacist intern, or dispensing practitioner shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation: (a) overutilization of the drug and drug

misuse; (b) underutilization of the drug; (c) therapeutic duplications, contradictions, and any warning labels or other information included with the drug; (d) interactions between the drug and any (i) other drugs which the patient is taking or has recently taken, (ii) diseases which the patient has, including any stages of the disease, and (iii) allergies that the patient may have; and (e) incorrect dosage or duration of treatment. NAC 639.707(4).

24. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder fails to strictly follow the instructions of a practitioner when filling, refilling, labeling, and dispensing a prescription. NAC 639.945(1)(d)

25. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder performed his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

26. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(12) upon the finding that the holder, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

27. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(15) upon the finding that the holder, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of NRS Chapter 639 or

other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision.

28. Each pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

29. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

30. If a pharmaceutical technician performs one of more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription, including but not limited to, verifying: (a) the selection and strength of the drug; the dosage form; and the labeling of the prescription. NAC 639.252(2).

31. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

32. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

33. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

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COUNT ONE

Unprofessional Conduct- Incompetent, Unskillful, or Negligent Conduct
(Respondent Opulencia)

34. Respondent Opulencia's failure to accurately verify the prescription dosage and duration in strict conformance with the instructions of prescribing practitioner prior to dispensing dispense RX# 1930061-2 and RX# 1930061-5 violated NAC 639.707(4)(e) and constituted unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest pursuant to NAC 639.945(1)(d) and/or (i). Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.210(12) and/or NRS 639.255(3).

35. Respondent Opulencia, as the managing pharmacist of Walgreens #05479 at the time of the violations alleged herein, is responsible, pursuant to NRS 639.220(1), for the misfills of RX# 1930061-2 and RX# 1930061-5, including pursuant to NAC 639.252(2) and NAC 639.702, if the misfills were attributable to the unprofessional conduct, including incorrect prescription data entry by pharmaceutical technician J.N. Zuniga, or any of the other pharmacy employee of Walgreens #05479 under the supervision of Respondent Opulencia. Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #05479)

36. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #05479, including Respondent Opulencia, or pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, Walgreens #05479 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #05479 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

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COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #02445)

37. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #02445, including pharmaceutical technician H.X. Jaghanan, pharmacist Julie Wan, or pharmacist D. Pham, Walgreens #02445 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #02445 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 6th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
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3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

[redacted] and [redacted]

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

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DATED this 24 day of December 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

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AUTHORIZED REPRESENTATIVE FOR
Walgreens Pharmacy #05479

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of December, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Walgreens Pharmacy #05479
385 E Silverado Ranch Blvd.
Las Vegas, NV 89183

Walgreens Pharmacy #02445
8337 S Park Circle
Orlando, FL 32819

William Stilling, Esq.
222 South Main St., Suite 500
Salt Lake City, UT 84101

Grace Opulencia, RPH
[redacted] Tamarus St.
Las Vegas, NV 89123

Grace Opulencia, RPH
[redacted] E Silverado Ranch Blvd.
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Darlene Nases
DARLENE NASES

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **WALGREENS PHARMACY #02445, Pharmacy License No. PH01964,** **GRACE OPULENCIA, RPh., Pharmacist Registration No. 15190,** **Respondent.**	**Case Nos. 21-169-PH-S** **21-169-PH-O** **21-169-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

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3. The Board has personal jurisdiction over Respondent Grace Opulencia, RPh. ("Opulencia"), because at the time of the events alleged herein, Respondent Opulencia held

Certificate of Registration No. 15190, issued by the Board, pursuant to NRS 639.127, on October 6, 2000, which authorized Respondent Opulencia to practice pharmacy in the State of Nevada.

4. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Opulencia was engaged in the practice of pharmacy at the pharmacy operated by Respondent Walgreens #05479 in the State of Nevada and Walgreens #02445 was operating a pharmacy which engaged in the practice of pharmacy into the State of Nevada.

PRIOR DISCIPLINE

(Respondent Opulencia)

5. On or about February 7, 2022, Respondent Opulencia was mailed a $500.00 Citation and Fine in Case No. 19-119-RPH-S for a medication misfill of Adderall XR capsules, 25mg wherein RX# 2969633 was short six capsules. Respondent Opulencia timely paid the $500.00 fine.

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6. In or about January of 2016, Respondent Walgreens #02445 a.k.a Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, entered into a Stipulation and Order in Case No. 15-028-RPH-S. In the Stipulation, Respondent Walgreens #02445 admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employee, who did not hold a Nevada pharmacist registration, had incorrectly verified a RX #3094107-3922, a prescription written for Zoloft 200mg as simvastatin 20 mg tablets (generic Zocor). Respondent Walgreens #02445 paid a fine of $1,000.00 and attorney's fees and costs of $495.00.

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RX# 1930061-2

11. On or about August 2, 2021, Dana Shepherd, P.A. issued a prescription for "Methotrexate 50mg/2ml injection solution," with directions stating "0.5 milliliter inject subcutaneously one time weekly," and "#1 Bottle(s), 30-day, Refills: 2." The prescription was electronically transmitted to Respondent Walgreens #05479 and designated as RX# 1930061-2.

12. On or about August 3, 2021, pharmaceutical technician H.X. Jaghanan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the data entry for RX# 1930061-2. The data entry performed by H.X. Jaghanan identified prescription at "Methotrexate 25mg/ml PF SI."

13. Pharmaceutical technician H.X. Jaghanan is not licensed to practice pharmacy in the State of Nevada.

14. On or about August 23, 2021, pharmacist Julie Wan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the "Pat/Pbr rev" and "Data Product Review" for RX# 1930061-2.

15. Pharmacist Julie Wan is not licensed to practice pharmacy in the State of Nevada.

16. On or about August 23, 2021, pharmacist D. Pham, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, overrode 5 DURs for RX# 1930061-2.

17. Pharmacist D. Pham is not licensed to practice pharmacy in the State of Nevada.

18. On or about August 23, 2021, pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, who was located at Walgreens #05479, filled RX# 1930061-2.

19. On or about August 24, 2021, Respondent Opulencia performed the final verification and incorrectly verified RX# 1930061-2 as preservative free.

20. On or about August 26, 2021, RX# 1930061-2 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-2.

RX# 1930061-5 - REFILL

21. On or about September 28, 2021, Respondent Opulencia performed the final verification on a refill of RX# 1930061 and incorrectly verified the prescription as preservative free.

22. On or about September 28, 2021, RX# 1930061-5 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-5.

APPLICABLE LAW

23. A pharmacist, pharmacist intern, or dispensing practitioner shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation: (a) overutilization of the drug and drug

misuse; (b) underutilization of the drug; (c) therapeutic duplications, contradictions, and any warning labels or other information included with the drug; (d) interactions between the drug and any (i) other drugs which the patient is taking or has recently taken, (ii) diseases which the patient has, including any stages of the disease, and (iii) allergies that the patient may have; and (e) incorrect dosage or duration of treatment. NAC 639.707(4).

24. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder fails to strictly follow the instructions of a practitioner when filling, refilling, labeling, and dispensing a prescription. NAC 639.945(1)(d)

25. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder performed his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

26. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(12) upon the finding that the holder, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

27. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(15) upon the finding that the holder, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of NRS Chapter 639 or

other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision.

28. Each pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

29. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

30. If a pharmaceutical technician performs one of more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription, including but not limited to, verifying: (a) the selection and strength of the drug; the dosage form; and the labeling of the prescription. NAC 639.252(2).

31. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

32. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

33. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

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COUNT ONE

Unprofessional Conduct- Incompetent, Unskillful, or Negligent Conduct
(Respondent Opulencia)

34. Respondent Opulencia's failure to accurately verify the prescription dosage and duration in strict conformance with the instructions of prescribing practitioner prior to dispensing dispense RX# 1930061-2 and RX# 1930061-5 violated NAC 639.707(4)(e) and constituted unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest pursuant to NAC 639.945(1)(d) and/or (i). Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.210(12) and/or NRS 639.255(3).

35. Respondent Opulencia, as the managing pharmacist of Walgreens #05479 at the time of the violations alleged herein, is responsible, pursuant to NRS 639.220(1), for the misfills of RX# 1930061-2 and RX# 1930061-5, including pursuant to NAC 639.252(2) and NAC 639.702, if the misfills were attributable to the unprofessional conduct, including incorrect prescription data entry by pharmaceutical technician J.N. Zuniga, or any of the other pharmacy employee of Walgreens #05479 under the supervision of Respondent Opulencia. Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #05479)

36. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #05479, including Respondent Opulencia, or pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, Walgreens #05479 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #05479 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

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COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #02445)

37. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #02445, including pharmaceutical technician H.X. Jaghanan, pharmacist Julie Wan, or pharmacist D. Pham, Walgreens #02445 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #02445 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 12th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GRACE OPULENCIA, RPh.,** **Pharmacist Registration No. 15190,** **Respondent.**	**Case No. 21-169-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____
GRACE OPULENCIA, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GRACE OPULENCIA, RPh.,** **Pharmacist Registration No. 15190,** **Respondent.**	**Case No. 21-169-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of DECEMBER, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of December, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Walgreens Pharmacy #05479
385 E Silverado Ranch Blvd.
Las Vegas, NV 89183

Walgreens Pharmacy #02445
8337 S Park Circle
Orlando, FL 32819

William Stilling, Esq.
222 South Main St., Suite 500
Salt Lake City, UT 84101

Grace Opulencia, RPH
[redacted] Tamarus St.
Las Vegas, NV 89123

Grace Opulencia, RPH
[redacted] E Silverado Ranch Blvd.
Las Vegas, NV 89183

Darlene Nases
DARLENE NASES

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FILED
FEB 27 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

SAM ZAND, MD,
Certificate of Registration No. CS22466,

Respondent.

Case No. 21-229-CS-A-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Sam Zand, MD, held a controlled substance registration, Certificate of Registration No. CS22466, issued by the Board.

FACTUAL ALLEGATIONS

2. From January 3, 2020, to January 3, 2022, Respondent's Prescription Monitoring Program (PMP) database patient request history report reveals a total of 55,102 queries. However, Respondent only issued 1,915 prescriptions (including refills) for 490 unique patients during that period.

3. Respondent regularly permitted unauthorized persons who were not licensed practitioners, including staff at 5 or more office locations, to use Respondent's credentials to access the PMP database and review patient utilization reports for patients of approximately 40 other practitioners, patients with whom Respondent had not established a bona fide therapeutic relationship.

4. Respondent failed to query and review for accuracy his MyRx prescriber activity report in the PMP database as required at least once every 6 months from 2015 through 2021, and during the 14-month period of July 7, 2022, to October 3, 2023.

APPLICABLE LAW

5. No person may prescribe a controlled substance except as authorized by law. 21 CFR § 1306.03; NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1).

6. A prescribing practitioner shall only issue a controlled substance prescription after review of a patient's utilization report in the PMP database in conformance with NRS 639.23507.

7. A practitioner shall review for accuracy his or her prescriber activity in the PMP database at least once every 6 months. NRS 453.164(7).

8. Patient utilization reports and all data in the PMP database constitute Protected Health Information (PHI); unauthorized access constitutes a criminal offense. 42 U.S.C. §1320d-6; 45 C.F.R. Part 160 and Part 164, Subparts A and E; NRS 453.164(8); NRS 453.552(2).

9. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

10. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

12. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has

committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of Law - Prescription Monitoring Program

13. By permitting unauthorized persons to access the PMP database and PHI using Respondent's credentials, as alleged in Paragraph 2 herein, and by failing to review for accuracy his MyRx prescriber activity, as alleged in paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 42 U.S.C. §1320d-6, 45 C.F.R. Part 160 and Part 164, Subparts A and E, NRS 453.164(7) and (8), NRS 453.321(1)(a), NRS 453.552(2), NRS 639.100(1) and/or NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT TWO

Unprofessional Conduct – Party to Fraudulent or Deceitful Practice or Transaction

14. By permitting unauthorized persons to access the PMP database and PHI using Respondent's credentials, as alleged in Paragraph 2 herein, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

15. By his acts as alleged herein, Respondent has performed his duties as the holder of controlled substance and dispensing practitioner registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By his acts as alleged herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of this Respondent.

Signed this 27th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAM ZAND, MD,** **Certificate of Registration No. CS22466,** **Respondent.**	**CASE NO. 21-229-CS-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, May 29, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 27th day of February 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAM ZAND, MD,** **Certificate of Registration No. CS22466,** **Respondent.**	**CASE NO. 21-229-CS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

SAM ZAND, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of February, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Sam Zand, MD
[redacted] Dean Martin Dr.
Las Vegas, NV 89103

Sam Zand, MD
[redacted] Wigwam Pkwy. [redacted]
Henderson, NV 89074

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

FILED
MAY 2 8 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAM ZAND, MD,** **Certificate of Registration No. CS22466,** **Respondent.**	**CASE NO. 21-229-CS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

#2: addressed at time of notice

#3: only at one location for a brief time period

#4: concern addressed

#5: prescriptions authorized

#6: PMP was reviewed

#7: see number 4

#8: no unauthorized access ongoing

#9: no fraudulent or deceitful practices

#10: only competent and skillful manners occurred

#11: no malicious violations

#12: only serving the public interest

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

Please note, I have tried to call the board many times to understand my options and submit this. I am not trying to admit or deny anything; I just want to learn. I will attend the hearing tomorrow to be honest about everything learned during this process. Thank you.

→ Update: I spoke with Mark at the Board, who said the hearing is not tomorrow and that a mistake was made in not sending me the notice that it got pushed back to next month or September.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 28 day of May, 2024.

SAM ZAND, MD

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FILED
MAR 18 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9842,** **Pharmacy License No. PH01422,** **ANUP CHABRA, RPH,** **Certificate of Registration No. 19283,** **Respondents.**	**Case Nos. 22-200-PH-N** **22-200-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has personal jurisdiction over Respondent CVS Pharmacy #9842 ("CVS #9842"), because at the time of the violations alleged herein, CVS #9842 held License No. PH01442, issued by the Board pursuant to NRS 639.230, authorizing it to operate as a pharmacy. Respondent Pharmacy has held License No. PH01442 since August 4, 1999.

2. The Board has personal jurisdiction over Respondent Anup Chabra, RPh. ("Chabra"), because at the time of the violations alleged herein, Chabra held Certificate of Registration No. 19283, issued by the Board pursuant to NRS 639.100 and NRS 639.127, authorizing Respondent to engage in the practice of pharmacy in the State of Nevada. Respondent Chabra has held Certificate of Registration No. 19283 since April 13, 2016.

3. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein, Chabra was engaged in the practice of pharmacy at the pharmacy operated by CVS #9842 in the State of Nevada.

PAST DISCIPLINE

4. On June 28, 2023, Chabra was issued a citation and fine in the amount of $500.00 for verification of an incorrect data entry performed by a pharmaceutical technician. Chabra dispensed the incorrect medication to the patient; however, the patient suffered no harm. Chabra paid the $500.00 fine on time.

FACTUAL ALLEGATIONS

5. CVS #9842 operated a pharmacy at 1980 N. Carson St., Carson City, NV 89701 at the time of the events alleged herein.

6. Chabra was employed as a floating pharmacist and working at CVS #9842 at the time of the events alleged herein.

7. On or about May 26, 2022, a new prescription for forty-five tablets of Nurtec ODT 75 MG was transmitted to CVS #9842 for patient T.R. and issued RX #1099126 by CVS #9842's computer system.

8. On or about June 21, 2022, RX #1099126 was verified by Chabra and dispensed to patient T.R.

9. On or about June 24, 2022, the Board received a complaint from patient T.R. stating that no patient counseling was offered or provided upon dispensation of RX #1099126. The complaint expressed concern about when the drug was to be taken and whether the drug was to be taken with food, with other medications, or whether to avoid caffeine.

10. As the pharmacist that performed the verification check of RX #1099126, Chabra was responsible to provide or ensure that counseling was provided to patient T.R. upon dispensation of RX #1099126.

11. The Board's investigator requested and received patient counseling records for RX #1099126 which indicates that patient counseling was offered but not accepted by patient T.R. on June 24, 2022.

12. CVS #9842's patient counseling records provided to the Board's investigator for RX #1099126 incorrectly state that patient T.R. was offered counseling but did not accept counseling for prescription RX #1099126.

APPLICABLE LAW

13. A pharmacist has a duty to counsel patients who are dispensed a prescription drug or device that has not previously been dispensed to the patient by that pharmacy or if in the judgment of the pharmacist counseling would further improve the drug therapy of the patient. NAC 639.707(1).

14. A pharmacist is required to communicate all matters which will enhance therapy through drugs with the patient or a person caring for the patient. The communication must include appropriate elements of counseling for the patient, as established by the Board. NRS 639.266(1).

15. When providing counseling, a pharmacist must include information, not limited to but including: the form of the dosage, dose, route of administration and duration of drug supply; any special directions and precautions for the preparation, administration and use of the drug or device by the patient; any common severe side effects, interactions and contraindications that may occur, recommendations to avoid these side effects, interactions or contraindications, and the action required if they occur. NAC 639.707(2)(b), (d), and (e).

16. A pharmacist has a duty to keep accurate records of whether counseling was given or refused by a patient. *See* NAC 639.707(6).

17. The Board may impose a fine against a pharmacist or pharmacy that fails to provide counseling to a patient and/or fails to maintain documentation of counseling given to a patient. NAC 639.955(1)(a-b).

18. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(4) upon a finding that the holder engaged in unprofessional conduct. Unprofessional conduct includes, performing any of his or her duties as the holder of a certificate or registration issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

19. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

20. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

21. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

22. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

COUNT ONE

Unprofessional Conduct – Failing to Provide Counseling
(Respondents Chabra and CVS #9842)

23. By failing to provide counseling to patient T.R., Respondent Chabra performed her duties in an incompetent, unskillful, or negligent manner because she failed to communicate *all matters* which could enhance therapy through drugs with the patient or a person caring for the patient. NRS 639.266(1); NAC 639.707(1); NAC 639.707(2)(b), (d), (e); and NAC 639.945(1)(i). Therefore, Respondent Chabra is subject to discipline by the Board pursuant to NRS 639.210(4); NAC 639.945(1)(i); NRS 639.255(1)(f) and (3); and NAC 639.955(1)(a).

24. As the owner of pharmacy, and/or pursuant to NRS 639.230(5), and/or NAC 639.945(2), and/or NAC 639.702, Respondent CVS #9842 is responsible the violations and for the acts its employees; therefore, CVS #9842 is subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT TWO

Unprofessional Conduct –Failure to Maintain an Accurate Record of Counseling (Respondents Chabra and CVS #9842)

25. By failing to create and/or correct the patient counseling record for RX #1099126 to ensure its accuracy, Respondent Chabra performed her duties in an incompetent, unskillful, or negligent manner. *See* NAC 639.707(6); NAC 639.945(1)(i). Therefore, Respondent Chabra is subject to discipline by the Board pursuant to NRS 639.210(4); NAC 639.945(1)(i); NRS 639.255(1)(f) and (3); and NAC 639.955(1)(b).

26. As the owner of pharmacy, and/or pursuant to NRS 639.230(5), and/or NAC 639.945(2), and/or NAC 639.702, Respondent CVS #9842 is responsible the violations and for the acts its employees; therefore, CVS #9842 is subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 1st day of March 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9842,** **Pharmacy License No. PH01422,** **Respondent.**	**Case No. 22-200-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 1st day of March 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9842,** **Pharmacy License No. PH01422,** **Respondent.**	**Case No. 22-200-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY #9842

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 18th day of March 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

CVS Pharmacy #9842
1980 N Carson St
Carson City, NV 89701

Brian J. Convery, Esq.
200 Campus Dr, Suite 310
Florham Park, NJ 07932

Anup Chabra, RPH
[redacted] Santa Monica Blvd #[redacted]
Los Angeles, CA 90046

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT I
BOARD COORDINATOR

51

FILED
MAR 18 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9842,** **Pharmacy License No. PH01422,** **ANUP CHABRA, RPH,** **Certificate of Registration No. 19283,** **Respondents.**	**Case Nos. 22-200-PH-N** **22-200-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has personal jurisdiction over Respondent CVS Pharmacy #9842 ("CVS #9842"), because at the time of the violations alleged herein, CVS #9842 held License No. PH01442, issued by the Board pursuant to NRS 639.230, authorizing it to operate as a pharmacy. Respondent Pharmacy has held License No. PH01442 since August 4, 1999.

2. The Board has personal jurisdiction over Respondent Anup Chabra, RPh. ("Chabra"), because at the time of the violations alleged herein, Chabra held Certificate of Registration No. 19283, issued by the Board pursuant to NRS 639.100 and NRS 639.127, authorizing Respondent to engage in the practice of pharmacy in the State of Nevada. Respondent Chabra has held Certificate of Registration No. 19283 since April 13, 2016.

3. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein, Chabra was engaged in the practice of pharmacy at the pharmacy operated by CVS #9842 in the State of Nevada.

PAST DISCIPLINE

4. On June 28, 2023, Chabra was issued a citation and fine in the amount of $500.00 for verification of an incorrect data entry performed by a pharmaceutical technician. Chabra dispensed the incorrect medication to the patient; however, the patient suffered no harm. Chabra paid the $500.00 fine on time.

FACTUAL ALLEGATIONS

5. CVS #9842 operated a pharmacy at 1980 N. Carson St., Carson City, NV 89701 at the time of the events alleged herein.

6. Chabra was employed as a floating pharmacist and working at CVS #9842 at the time of the events alleged herein.

7. On or about May 26, 2022, a new prescription for forty-five tablets of Nurtec ODT 75 MG was transmitted to CVS #9842 for patient T.R. and issued RX #1099126 by CVS #9842's computer system.

8. On or about June 21, 2022, RX #1099126 was verified by Chabra and dispensed to patient T.R.

9. On or about June 24, 2022, the Board received a complaint from patient T.R. stating that no patient counseling was offered or provided upon dispensation of RX #1099126. The complaint expressed concern about when the drug was to be taken and whether the drug was to be taken with food, with other medications, or whether to avoid caffeine.

10. As the pharmacist that performed the verification check of RX #1099126, Chabra was responsible to provide or ensure that counseling was provided to patient T.R. upon dispensation of RX #1099126.

11. The Board's investigator requested and received patient counseling records for RX #1099126 which indicates that patient counseling was offered but not accepted by patient T.R. on June 24, 2022.

12. CVS #9842's patient counseling records provided to the Board's investigator for RX #1099126 incorrectly state that patient T.R. was offered counseling but did not accept counseling for prescription RX #1099126.

APPLICABLE LAW

13. A pharmacist has a duty to counsel patients who are dispensed a prescription drug or device that has not previously been dispensed to the patient by that pharmacy or if in the judgment of the pharmacist counseling would further improve the drug therapy of the patient. NAC 639.707(1).

14. A pharmacist is required to communicate all matters which will enhance therapy through drugs with the patient or a person caring for the patient. The communication must include appropriate elements of counseling for the patient, as established by the Board. NRS 639.266(1).

15. When providing counseling, a pharmacist must include information, not limited to but including: the form of the dosage, dose, route of administration and duration of drug supply; any special directions and precautions for the preparation, administration and use of the drug or device by the patient; any common severe side effects, interactions and contraindications that may occur, recommendations to avoid these side effects, interactions or contraindications, and the action required if they occur. NAC 639.707(2)(b), (d), and (e).

16. A pharmacist has a duty to keep accurate records of whether counseling was given or refused by a patient. *See* NAC 639.707(6).

17. The Board may impose a fine against a pharmacist or pharmacy that fails to provide counseling to a patient and/or fails to maintain documentation of counseling given to a patient. NAC 639.955(1)(a-b).

18. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(4) upon a finding that the holder engaged in unprofessional conduct. Unprofessional conduct includes, performing any of his or her duties as the holder of a certificate or registration issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

19. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

20. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

21. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

22. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

COUNT ONE

Unprofessional Conduct – Failing to Provide Counseling
(Respondents Chabra and CVS #9842)

23. By failing to provide counseling to patient T.R., Respondent Chabra performed her duties in an incompetent, unskillful, or negligent manner because she failed to communicate *all matters* which could enhance therapy through drugs with the patient or a person caring for the patient. NRS 639.266(1); NAC 639.707(1); NAC 639.707(2)(b), (d), (e); and NAC 639.945(1)(i). Therefore, Respondent Chabra is subject to discipline by the Board pursuant to NRS 639.210(4); NAC 639.945(1)(i); NRS 639.255(1)(f) and (3); and NAC 639.955(1)(a).

24. As the owner of pharmacy, and/or pursuant to NRS 639.230(5), and/or NAC 639.945(2), and/or NAC 639.702, Respondent CVS #9842 is responsible the violations and for the acts its employees; therefore, CVS #9842 is subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT TWO

Unprofessional Conduct –Failure to Maintain an Accurate Record of Counseling (Respondents Chabra and CVS #9842)

25. By failing to create and/or correct the patient counseling record for RX #1099126 to ensure its accuracy, Respondent Chabra performed her duties in an incompetent, unskillful, or negligent manner. *See* NAC 639.707(6); NAC 639.945(1)(i). Therefore, Respondent Chabra is subject to discipline by the Board pursuant to NRS 639.210(4); NAC 639.945(1)(i); NRS 639.255(1)(f) and (3); and NAC 639.955(1)(b).

26. As the owner of pharmacy, and/or pursuant to NRS 639.230(5), and/or NAC 639.945(2), and/or NAC 639.702, Respondent CVS #9842 is responsible the violations and for the acts its employees; therefore, CVS #9842 is subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 18th day of March 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ANUP CHABRA, RPH,** **Certificate of Registration No. 19283,** **Respondent.**	**Case No. 22-200-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 19th day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ANUP CHABRA, RPH,** **Certificate of Registration No. 19283,** **Respondent.**	**Case No. 22-200-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

ANUP CHABRA, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of April 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Anup Chabra
[redacted] Harvard Way Apt #[redacted]
Reno, NV 89502

Darlene Nases
DARLENE NASES
BOARD COORDINATOR

5J

FILED
FEB 27 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #03845, Pharmacy License No. PH01064, and** **YOOJIN JEONG, RPH, Certificate of Registration No. 18030,** **Respondents.**	**CASE NOS. 22-366-PH-S** **22-366-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Yoojin Jeong, RPh (Jeong), Certificate of Registration No. 18030, was a pharmacist registered with the Board, and Respondent Walgreens Pharmacy #03845, Pharmacy License No. PH01064, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Jeong was employed as pharmacist by Walgreens Pharmacy #03845 at the time of the events alleged herein.

3. On or about June 16, 2022, in the course of dispensing prescription no. 4180718 for Doxycycline Monohydrate and prescription no. 4180719 for Clindamycin 1% topical solution to patient P.C. at Walgreens Pharmacy #03845, Jeong also dispensed prescription no. 4147239

for Valsartan/HCTZ 320 mg/12.5m tablets, intended for patient D.C., a patient with the same last name as patient P.C.

4. P.C. ingested the erroneously dispensed medication for 18 days, and experienced negative medical outcomes including severe headaches.

COUNT ONE

Error in Dispensing Prescription/Unprofessional Conduct/ Pharmacy Responsibility
(Respondents Jeong and Walgreens Pharmacy #03845)

5. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

6. Respondent Jeong engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he erroneously dispensed prescription no. 4147239 to P.C., resulting in patient harm, and is therefore subject to discipline pursuant to NRS 639.210(4).

7. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

8. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Walgreens Pharmacy #03845 is responsible for those violations, including all errors and omissions of Jeong, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses and certificates of registrations of these Respondents.

Signed this 27th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #03845,** **Pharmacy License No. PH01064,** **Respondent.**	**CASE NO. 22-366-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, May 29, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 27th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #03845,** **Pharmacy License No. PH01064,** **Respondent.**	**CASE NO. 22-366-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____
TYPE OR PRINT NAME

_____
AUTHORIZED REPRESENTATIVE FOR WALGREENS PHARMACY #03845

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of February, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Yoojin Jeong, RPH
[redacted] Bachelor Button St.
Las Vegas, NV 89138

Walgreens Pharmacy #03845
2280 N. Las Vegas Blvd.
North Las Vegas, NV 89030-5803

William Stilling, Esq.
222 South Main Street, Suite 500
Salt Lake City, Utah 84101

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

5K

FILED
FEB 27 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #03845, Pharmacy License No. PH01064, and** **YOOJIN JEONG, RPH, Certificate of Registration No. 18030,** **Respondents.**	**CASE NOS. 22-366-PH-S** **22-366-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Yoojin Jeong, RPh (Jeong), Certificate of Registration No. 18030, was a pharmacist registered with the Board, and Respondent Walgreens Pharmacy #03845, Pharmacy License No. PH01064, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Jeong was employed as pharmacist by Walgreens Pharmacy #03845 at the time of the events alleged herein.

3. On or about June 16, 2022, in the course of dispensing prescription no. 4180718 for Doxycycline Monohydrate and prescription no. 4180719 for Clindamycin 1% topical solution to patient P.C. at Walgreens Pharmacy #03845, Jeong also dispensed prescription no. 4147239

for Valsartan/HCTZ 320 mg/12.5m tablets, intended for patient D.C., a patient with the same last name as patient P.C.

4. P.C. ingested the erroneously dispensed medication for 18 days, and experienced negative medical outcomes including severe headaches.

COUNT ONE

Error in Dispensing Prescription/Unprofessional Conduct/ Pharmacy Responsibility
(Respondents Jeong and Walgreens Pharmacy #03845)

5. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

6. Respondent Jeong engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he erroneously dispensed prescription no. 4147239 to P.C., resulting in patient harm, and is therefore subject to discipline pursuant to NRS 639.210(4).

7. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

8. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Walgreens Pharmacy #03845 is responsible for those violations, including all errors and omissions of Jeong, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses and certificates of registrations of these Respondents.

Signed this 21st day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **YOOJIN JEONG, RPH,** **Certificate of Registration No. 18030,** **Respondent.**	**CASE NO. 22-366-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, May 29, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 27th day of February 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **YOOJIN JEONG, RPH,** **Certificate of Registration No. 18030,** **Respondent.**	**CASE NO. 22-366-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

YOOJIN JEONG, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of February, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Yoojin Jeong, RPH
[redacted] Bachelor Button St.
Las Vegas, NV 89138

Walgreens Pharmacy #03845
2280 N. Las Vegas Blvd.
North Las Vegas, NV 89030-5803

William Stilling, Esq.
222 South Main Street, Suite 500
Salt Lake City, Utah 84101

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

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FILED
JUN 18 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **THOMAS SCHOTIK, RPH, Certificate of Registration No. 08312,** **Respondents.**	**CASE NOS. 23-063-PH-S** **23-063-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Thomas Schotik, RPh (Schotik), Certificate of Registration No. 08312, was a pharmacist registered with the Board, and Respondent American Wellness Pharmacy, Pharmacy License No. PH02705, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Schotik was employed as managing pharmacist by American Wellness Pharmacy at the time of the events alleged herein.

3. On or about November 16, 2023, Board staff inspected American Wellness Pharmacy's premises and operations and determined that the pharmacy was compounding drug products in violation of law.

4. American Wellness Pharmacy compounded and sold drug products using active ingredients that (1) do not have a United States Pharmacopoeia-National Formulary monograph;

(2) are not a part of an FDA approved drug product, or (3) are not authorized to be used in pharmacy compounding pursuant to 21 USC § 353a(b)(1) or the regulations adopted pursuant thereto. Specifically, the pharmacy is advertising and dispensing compounded injectable peptides, including, without limitation, BPC-157, CJC 1295, Dihexa, GHK-CU, GAC, Kisspeptin, MK-677, PT-141, Thymosin Alpha-1, and Thymosin Beta-4.

5. American Wellness Pharmacy compounded and sold high-risk sterile products with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD, including, without limitation:

A. Multiple vials of compounded semaglutide 1.2mg/ml #30mL were found refrigerated with a lot date of 11/3/2023 and expiration date of 12/18/2023 with "refrigerate" on the label, with no studies on file to support an extended BUD.

B. Myers cocktail 50mL vials for office use were found refrigerated with a lot batch date of 10/25/2023 and 45-day BUD listed on the vial, with no studies on file to support an extended BUD.

C. Glutathione 200mg/ml 10ml vials were found refrigerated with a lot batch date of 11/15/2023 and a 90-day BUD, with no documentation to support the extended BUD.

D. Testosterone cypionate 50mg/ml with a 60-day BUD at room temperature lacking a potency documentation to justify the BUD.

APPLICABLE LAW

6. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661-.690, *inclusive*, and related federal law, 21 U.S.C. § 353a, establishing national standards for compounding medications.

7. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

8. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

9. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

10. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including, without limitation, maintenance of standards of purity of the pharmaceutical stock and recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1), NAC 639.510 and/or NAC 639.702.

11. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

COUNT ONE

Violations of Law – Drug Compounding

12. American Wellness Pharmacy's personnel violated NAC 639.67019, NAC 639.67067, NAC 639.67071 and/or NAC 639.757 and related provisions of 21 U.S.C. § 353a as alleged in paragraphs 3-5 herein.

13. As the managing pharmacist of American Wellness Pharmacy at the time of the violations alleged herein, Schotik is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1), NAC 639.510 and/or NAC 639.702.

14. As the pharmacy/pharmacy owner at which the violations alleged herein occurred, American Wellness Pharmacy is responsible for those violations, including all errors and omissions of the pharmacy personnel, and subject to discipline pursuant to pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

COUNT TWO

Unprofessional Conduct – Drug Compounding

15. By the acts alleged herein, Schotik and other personnel of American Wellness Pharmacy engaged in unprofessional conduct as defined in NAC 639.945(1)((i). Schotik is therefore subject to discipline pursuant to NRS 639.210(4), and American Wellness Pharmacy is therefore subject to discipline pursuant to NAC 639.945(2) and 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses and certificates of registration of these Respondents.

Signed this 6th day of June 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY,** **Pharmacy License No. PH02705,** **Respondent.**	**CASE NO. 23-063-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 19th day of June 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705,** **Respondent.**	**CASE NO. 23-063-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR AMERICAN WELLNESS PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of June 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

American Wellness Pharmacy
2755 S. Jones Blvd Ste 100A
Las Vegas, NV 89146

Thomas Schotik, RPH
[redacted] Sean Darin Circle
Las Vegas, NV 89146

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

FILED
JUL 19 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705,** **Respondent.**	**CASE NO. 23-063-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

None.

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows: See attached.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 17 day of July 2024.

Trevor Waite

AUTHORIZED REPRESENTATIVE FOR AMERICAN WELLNESS PHARMACY

American Wellness Pharmacy Responses

1. In responding to paragraph 1 of the Notice of Intended Action and Accusation (the "Notice"), Respondent American Wellness Pharmacy ("AMP") admits the allegations set contained therein.

2. In responding to paragraph 3 of the Notice, AMP admits the allegations contained therein.

3. In responding to paragraph 3 of the Notice, AMP admits that Board Staff inspected AMP's premises on or about November 16, 2023, and denies it has violated any laws.

4. In responding to paragraph 4 of the Notice, AMP denies the allegations and states that the inspection occurred within less than a month of the category 2 list being published and that at the time of the inspection AMP was in the process of getting in compliance but that thereafter all category 2 medications were removed from our formulary that was used to advertise to clinics. Additionally, AMP states that it had all required certificates of analysis. *See* attached **Exhibit A.**

5. In responding to paragraph 5 of the Notice, AMP admits the allegations, but states that corrective action was immediately taken including isolation and proper destruction of the lots indicated as well as a comprehensive list of all beyond use dates with testing was generated thereafter. *See* **Exhibit B.** Further, AMP subsequently replaced the AMP pharmacist in charge and as of approximately June 20, 2024, Mr. Schotik was no longer the AMP PIC. It is important to note that AMP made this PIC change prior to receipt of the Notice. Further, AMP has labeled all required medications with the proper 3-day stickers. *Id.*

6. In responding to paragraphs 6 -9 of the Notice, AMP states that these paragraphs do not set forth facts that require AMP to admit or deny. However, to the extent an admit or deny response is required, AMP states that it is without sufficient knowledge and information upon which to base the truth or falsity of the content of these paragraphs and therefore must deny the same.

7. In responding to paragraph 10 of the Notice, AMP states that the paragraph does not set forth a set of facts that require an admit or deny response from AMP. However, to the extent an admit or deny response is required, AMP admits the information contained therein.

8. In responding to paragraph 11 of the Notice, AMP states that the paragraph does not set forth facts that require an admit or deny response from AMP. However, to the extent an admit or deny response is required, AMP states that it is without sufficient knowledge and information upon which to base the truth or falsity of the content of the paragraph and therefore must deny the same.

9. In responding to paragraph 12 of the Notice, AMP states that this paragraph calls for a legal conclusion and AMP is therefore without sufficient knowledge and information upon which to base the truth or falsity of the content of the paragraph and therefore must deny the same. Subject to, and notwithstanding that response, AMP further incorporates and restates its responses from paragraphs 3-5 as if fully set forth herein.

10. In responding to paragraphs 13 and 14 of the Notice, AMP states that these paragraphs call for legal conclusions and AMP is therefore without sufficient knowledge and information upon which to base the truth or falsity of the content of the paragraphs and therefore must deny the same.

11. In responding to paragraph 15 of the Notice, AMP states that this paragraph calls for a legal conclusion and AMP is therefore without sufficient knowledge and information upon which to base the truth or falsity of the content of the paragraph and therefore must deny the same.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 484496-01
LOT #: 08/07/2018 9:33:09AM
DESCRIPTION: ALPROSTADIL 1000UG/ML
DATE RECEIVED: 08/08/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in brown bags (8 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Alprostadil Specifications = 90.0% - 115.0%	1000	µg/mL	1021.0635	102.1%	HPLC	11/9/2018

Time = 3 Months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Katherine Coats - Chemist II

11/09/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

3577

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452677-01
LOT #: 02/22/2018 1:56:56PM
DESCRIPTION: NANDROLONE DECANOATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials w/2 mL each In brown bags (14 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	MBI-144	08/23/2018

Time = 6 months of testing at pre-defined timepoints.
MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

09/10/2018

Jessica Pagan - Microbiologist — Date Reported

Sterility – 18 day sterility report. In accordance with the test methodology, the sample was incubated for a minimum of 18 days.

Fungal – 18 day fungal report. In accordance with the test methodology, the sample was incubated for a minimum of 18 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
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FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452677-01
LOT #: 02/22/2018 1:56:56PM
DESCRIPTION: NANDROLONE DECANOATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials w/2 mL each in brown bags (14 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Nandrolone Decanoate Specifications = 90.0% - 110.0%	200	mg/mL	196.7838	98.4%	HPLC	8/24/2018

Time = 6 months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Katherine Coats - Chemist II

08/24/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

3579

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
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Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452677-01
LOT #: 02/22/2018 1:56:56PM
DESCRIPTION: NANDROLONE DECANOATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials w/2 mL each in brown bags (14 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days (subcultured) *	MBI-144	08/23/2018

Time = 6 months of testing at pre-defined timepoints.
MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.
* This is not a final result. After 14 days of incubation, the material being tested rendered the media turbid so that the presence or absence of microbial growth cannot be readily determined by visual examination. Per USP <71>, the sample will be inoculated into new growth media and incubated for an additional 4 days before the test is complete. An updated report will be issued at the conclusion of the test.

09/06/2018

Jessica Pagan - Microbiologist — Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
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Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 365308-01
LOT #: 08162016G10
DESCRIPTION: Papaverine 30 mg/mL Inj
DATE RECEIVED: 08/17/2016
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Three 5 mL amber vials w/3 mL each in clear bags (8 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	MBI-144	01/12/2017

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.
Time = 5 months of testing at pre-defined timepoints.

01/26/2017

Maurice Rogers - Microbiologist — Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA

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OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
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Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 365308-01
LOT #: 08162016G10
DESCRIPTION: Papaverine 30 mg/mL Inj
DATE RECEIVED: 08/17/2016
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Three 5 mL amber vials w/3 mL each in clear bags (8 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Papaverine HCl Specifications = 95% - 105%	30	mg/mL	30.438	101.5%	HPLC	1/16/2017

The analyses referenced in this report are for non-cGMP purpose only. The method(s) used for testing are not validated. Specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Time = 5 months of testing at pre-defined timepoints.

Wen Yang - Chemist

01/16/2017
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

3582

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 484511-01
LOT #: 08/07/2018 9:33:46AM
DESCRIPTION: PHENTOLAMINE 30MG/ML
DATE RECEIVED: 08/08/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in brown bags (8 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	MBI-144	11/08/2018

Time = 3 Months of testing at pre-defined timepoints.
MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Kerri Hirst - Microbiologist III

11/26/2018
Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V7 09/29/2014

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 484511-01
LOT #: 08/07/2018 9:33:46AM
DESCRIPTION: PHENTOLAMINE 30MG/ML
DATE RECEIVED: 08/08/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in brown bags (8 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Phentolamine Mesylate Specifications = 90.0% - 110.0%	30	mg/mL	31.2159	104.1%	HPLC	11/9/2018

Time = 3 Months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Katherine Coats - Chemist II

11/12/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

3584

Certificate of Analysis

CLIENT : Precision Specialty Pharmacy
DESCRIPTION : TESTOSTERONE CYPIONATE 50mg/ml
LOT # : 11/4/2022 9:45:12 PM
ARL # : 879409
FORMULATION ID : TESTOSTERONE CYPIONATE 50MG/ML

DATE RECEIVED : 11/08/2022
STORAGE : 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Endotoxin	MBI-145	Report Value	<10.00 EU / mL	01/10/2023
Sterility - (PRELIMINARY)	MBI-144	Sterile	No Growth at 3 Days	01/09/2023

Notes

Sterility: MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Time = Day 60 of testing at pre-defined timepoints.

Megan Adler - Microbiologist I

01/12/2023
Date

ARL BIO PHARMA

Certificate of Analysis

CLIENT : Precision Specialty Pharmacy
DESCRIPTION : TESTOSTERONE CYPIONATE
LOT # : 11/4/2022 9:45:12 PM
ARL # : 879169
FORMULATION ID : TESTOSTERONE CYPIONATE 50MG/ML

DATE RECEIVED : 11/08/2022
STORAGE : 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Assay - Testosterone Cypionate	HPLC / AMIF-1874	90.0% - 110.0%	97.2% (48.6148mg / 1mL)	11/08/2022

Notes

Assay: The referenced method (AMIF) used for testing was validated for non-cGMP analysis of the stated analyte(s). The client should verify the specifications and analyte(s) reported are correct for the compounded formulation.

Katie Coats - Senior Chemist

11/11/2022
Date

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452686-01
LOT #: 02/22/2018 1:56:43PM
DESCRIPTION: TESTOSTERONE CYPIONATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in brown bags (14 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Testosterone Cypionate Specifications = 90.0% - 110.0%	200	mg/mL	199.5923	99.8%	HPLC	8/24/2018

Time = 6 months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Katherine Coats - Chemist II

08/24/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

3587

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
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Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452686-01
LOT #: 02/22/2018 1:56:43PM
DESCRIPTION: TESTOSTERONE CYPIONATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in brown bags (14 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days (subcultured) *	MBI-144	08/28/2018

Time = 6 months of testing at pre-defined timepoints.
MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.
* This is not a final result. After 14 days of incubation, the material being tested rendered the media turbid so that the presence or absence of microbial growth cannot be readily determined by visual examination. Per USP <71>, the sample will be inoculated into new growth media and incubated for an additional 4 days before the test is complete. An updated report will be issued at the conclusion of the test.

09/11/2018

Jessica Pagan - Microbiologist — Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA

Certificate of Analysis

CLIENT : American Wellness Pharmacy
DESCRIPTION : Testosterone propionate 100mg/mL
LOT # : 3/27/2023 10:32:18 AM
ARL # : 923120
FORMULATION ID : 3/27/2023 10:32:18 AM

DATE RECEIVED : 05/01/2023
STORAGE : 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Assay - Testosterone Propionate	HPLC / AMIF-1874	88.0% - 112.0%	97.0% (97.0259mg / 1mL)	05/18/2023

Notes

Assay: The referenced method (AMIF) used for testing was validated for non-cGMP analysis of the stated analyte(s). The client should verify the specifications and analyte(s) reported are correct for the compounded formulation.

Amber Fisher

Amber Fisher - Data Review Chemist I

05/19/2023

Date

ARL BIO PHARMA

Certificate of Analysis

CLIENT : American Wellness Pharmacy
DESCRIPTION : Testosterone propionate 100mg/mL
LOT # : 3/27/2023 10:32:18 AM
ARL # : 923120
FORMULATION ID : 3/27/2023 10:32:18 AM

DATE RECEIVED : 05/01/2023
STORAGE : 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Endotoxin	MBI-145	Report Value	<10.00 EU / mL	05/18/2023
Sterility - (PRELIMINARY)	MBI-144	Sterile	No Growth at 5 Days	05/17/2023

Notes

Sterility: MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Megan Adler - Microbiologist I

05/22/2023
Date

ARL BIO PHARMA

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 541635-01
LOT #: 06/17/2019 9:08:23AM
DESCRIPTION: TRIMIX #3 ALPROSTADIL 25UG/ML PHENTOLAMINE 1MG/ML PAPAVERIN
DATE RECEIVED: 06/18/2019
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Four 5 mL clear vials w/2.5 mL each in clear bags (12 total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Alprostadil Specifications = 90.0% - 115.0%	25	mcg/mL	23.1760	92.7%	AMIF-1867	8/19/2019
Papaverine HCl Specifications = 95.0% - 105.0%	28.2	mg/mL	28.6775	101.7%	AMIF-1868	8/20/2019
Phentolamine Mesylate Specifications = 90.0% - 110.0%	1.0	mg/mL	0.9371	93.7%	AMIF-1868	8/20/2019

Time = Day 60 of testing at pre-defined timepoints.

The referenced method (AMIF) used for testing was validated for non-cGMP analysis of the stated analyte(s). The client should verify the specifications and analyte(s) reported are correct for the compounded formulation.

Katherine Coats - Chemist II

08/21/2019
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

3591

ARL BIO PHARMA

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 541635-01
LOT #: 06/17/2019 9:08:23AM
DESCRIPTION: TRIMIX #3 ALPROSTADIL 25UG/ML PHENTOLAMINE 1MG/ML PAPAVERIN
DATE RECEIVED: 06/18/2019
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Four 5 mL clear vials w/2.5 mL each in clear bags (12 total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 3 Days	MBI-144	08/16/2019

Time = Day 60 of testing at pre-defined timepoints.

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Madeline Kennedy

Madeline Kennedy - Microbiologist II

08/19/2019
Date Reported

ARL Form QUF-078-V6 11/26/2012

Results reported above relate only to the sample that was tested.

3592

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
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Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 460869-01
LOT #: 04/05/2018 11:16:08
DESCRIPTION: TRIMIX #9 ALPROSTADIL 50UG/ML PHENTOLAMINE 1.5MG/ML PAPAVERI
DATE RECEIVED: 04/06/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Four 5 mL amber vials w/2 mL each in clear bags (12 total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	MBI-144	06/06/2018

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.
Time = 2 months of testing at pre-defined timepoints.

Kerri Hirst

06/20/2018

Kerri Hirst - Microbiologist II — Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 460869-01
LOT #: 04/05/2018 11:16:08
DESCRIPTION: TRIMIX #9 ALPROSTADIL 50UG/ML PHENTOLAMINE 1.5MG/ML PAPAVERI
DATE RECEIVED: 04/06/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Four 5 mL amber vials w/2 mL each in clear bags (12 total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Alprostadil Specifications = 90.0% - 115.0%	50	µg/mL	47.7501	95.5%	HPLC	6/9/2018
Papaverine HCl Specifications = 95.0% - 105.0%	27	mg/mL	28.1841	104.4%	HPLC	6/7/2018
Phentolamine Mesylate Specifications = 90.0% - 110.0%	1.5	mg/mL	1.5650	104.3%	HPLC	6/7/2018

Time = 2 months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Wen Yang - Chemist

06/11/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

3594

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 460887-01
LOT #: 04/05/2018 11:30:17
DESCRIPTION: VITAMIN D3 100,000 UNITS/ML
DATE RECEIVED: 04/06/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in clear bags (6 total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days (subcultured) *	MBI-144	06/06/2018

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Time = 2 months of testing at pre-defined timepoints.

* This is not a final result. After 14 days of incubation, the material being tested rendered the media turbid so that the presence or absence of microbial growth cannot be readily determined by visual examination. Per USP <71>, the sample will be inoculated into new growth media and incubated for an additional 4 days before the test is complete. An updated report will be issued at the conclusion of the test.

Kerri Hirst

06/20/2018

Kerri Hirst - Microbiologist II — Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 460887-01
LOT #: 04/05/2018 11:30:17
DESCRIPTION: VITAMIN D3 100,000 UNITS/ML
DATE RECEIVED: 04/06/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in clear bags (6 total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Vitamin D3 (Cholecalciferol) Specifications = 90.0% - 120.0%	100000	Units/mL	108454	108.5%	HPLC	6/8/2018

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Time = 2 months of testing at pre-defined timepoints.

Wen Yang - Chemist

06/08/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

3596

HIGH-RISK STERILE PRODUCTS BEYOND USE DATE

Document Created: 12/7/2023
Last Update: 03/20/2024

COMPOUND	STRENGTH	STORAGE	BUD
ALPHA LIPOIC ACID	25 MG/ML	REFRIGERATED	30 DAYS (PCCA)
ASCORBIC ACID	500 MG/ML	FROZEN	45 DAYS
BIMIX CUSTOM	CUSTOM	FROZEN	45 DAYS
BREMELANOTIDE (PT-141)	10 MG/ML	FROZEN	45 DAYS
ELAMIPRETIDE (SS-31)	2 MG/ML	FROZEN	45 DAYS
GAC (GLUTAMINE/ARGININE/CARNITINE)	20/50/100 MG/ML	FROZEN	45 DAYS
GLUTATHIONE	200 MG/ML	FROZEN	45 DAYS
GONADORELIN	2 MG/ML	FROZEN	45 DAYS
HEXARELIN	1 MG/ML	FROZEN	45 DAYS
KETAMINE HCL	50 MG/ML	REFRIGERATED	3 DAYS
KETAMINE HCL	100 MG/ML	REFRIGERATED	3 DAYS
L-CARNITINE	250 MG/ML	FROZEN	45 DAYS
LIDOCAINE HCL	1%	FROZEN	45 DAYS
LIDOCAINE	2%	FROZEN	45 DAYS
LIDOCAINE W/ EPINEPHRINE	1% 1:100000	FROZEN	45 DAYS
LIDOCAINE W/ EPINEPHRINE	2% 1:100000	FROZEN	45 DAYS
LIRAGLUTIDE	2.5 MG/ML	FROZEN	45 DAYS
LONG R3-IGF-1 (IGF-LR3)	200 MCG/ML	FROZEN	45 DAYS
MIC	25/50/25 MG/ML	FROZEN	45 DAYS
MIC B-12	25/50/25/1 MG/ML	FROZEN	45 DAYS

HIGH-RISK STERILE PRODUCTS BEYOND USE DATE

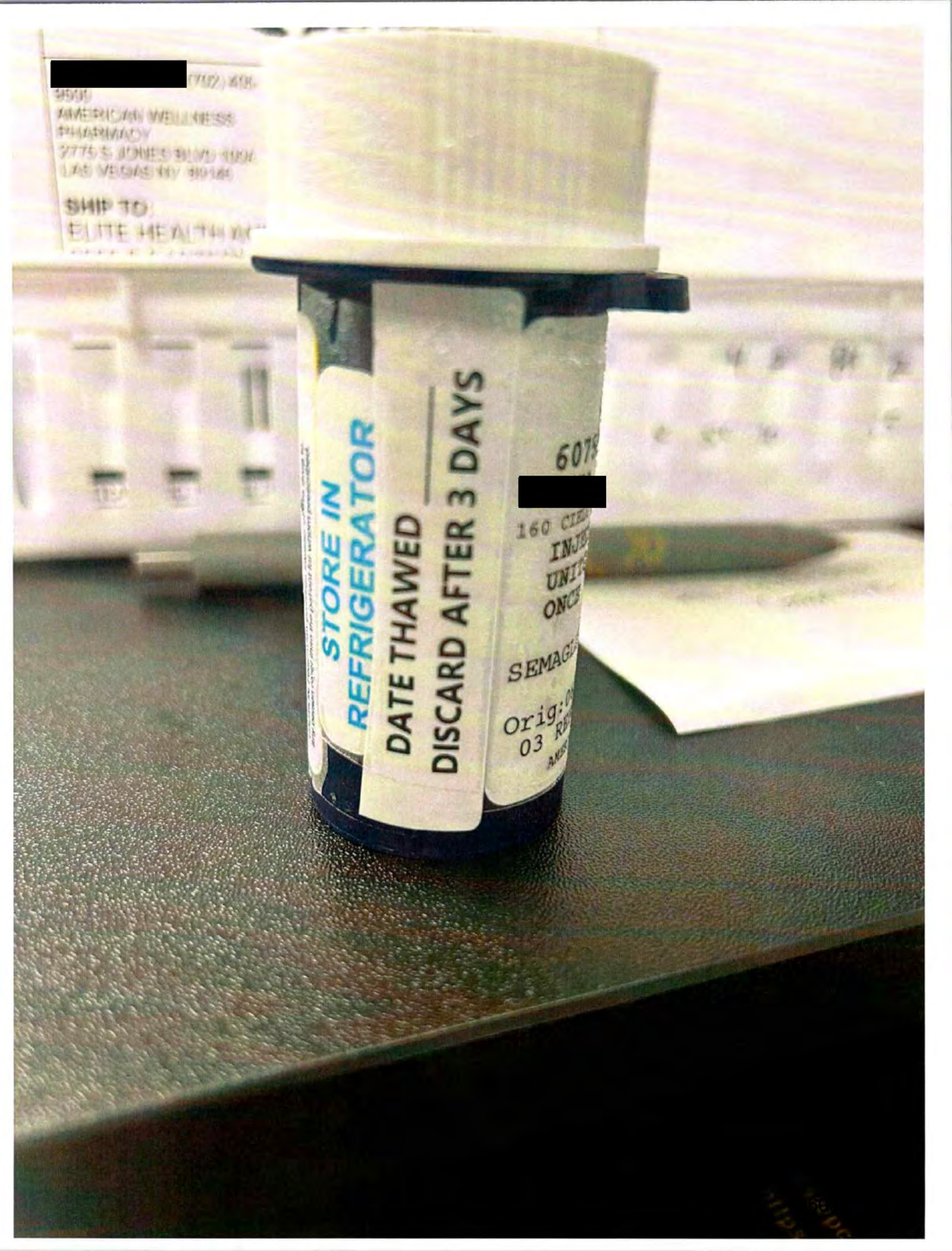
Document Created: 12/7/2023
Last Update: 03/20/2024

MYERS COCKTAIL		FROZEN	45 DAYS
NAD+	25 MG/ML	FROZEN	45 DAYS
NANDROLONE DECANOATE	200 MG/ML	ROOM TEMPERATURE	180 DAYS
PAPAVERINE	30 MG/ML	REFRIGERATED	90 DAYS
PDA (PENTADECAPEPTIDE ARGINATE)	2 MG/ML	FROZEN	45 DAYS
PENTOSAN POLYSULFATE SODIUM	250 MG/ML	FROZEN	45 DAYS
PGE ALPROSTADIL	20 MCG/ML	FROZEN	45 DAYS
PGE ALPROSTADIL	40 MCG/ML	FROZEN	45 DAYS
PGE ALPROSTADIL	80 MCG/ML	FROZEN	45 DAYS
PGE ALPROSTADIL	100 MCG/ML	FROZEN	45 DAYS
PGE ALPROSTADIL	150 MCG/ML	FROZEN	45 DAYS
PGE ALPROSTADIL (STOCK SOLUTION)	1000 MCG/ML	REFRIGERATED	90 DAYS
PHENTOLAMINE MESYLATE	30 MG/ML	REFRIGERATED	90 DAYS
QUADMIX CUSTOM	CUSTOM	FROZEN	45 DAYS
SEMAGLUTIDE	1.2 MG/ML	FROZEN	45 DAYS
SERMORELIN	2 MG/ML	FROZEN	45 DAYS
TESTOSTERONE CYPIONATE	50 MG/ML	ROOM TEMPERATURE	60 DAYS
TESTOSTERONE CYPIONATE	200 MG/ML	ROOM TEMPERATURE	180 DAYS
TESTOSTERONE PROPIONATE	100 MG/ML	ROOM TEMPERATURE	50 DAYS
TIRZEPATIDE	12 MG/ML	FROZEN	45 DAYS
TRIMIX #1		FROZEN	45 DAYS
TRIMIX #2		FROZEN	45 DAYS

HIGH-RISK STERILE PRODUCTS BEYOND USE DATE

Document Created: 12/7/2023
Last Update: 03/20/2024

TRIMIX #3		REFRIGERATED	60 DAYS
TRIMIX #8		FROZEN	45 DAYS
TRIMIX #9		REFRIGERATED	60 DAYS
TRIMIX CUSTOM	CUSTOM	FROZEN	45 DAYS
VITAMIN A	100,000 IU/ML	ROOM TEMPERATURE	1 DAY
VITAMIN B COMPLEX (B1, B2, B3, B5, B6)	10/1/10/1/1 MG/ML	FROZEN	45 DAYS
VITAMIN B COMPLEX W/ B12 (B1, B2, B3, B5, B6, B12)	10/1/10/1/1/0.1 MG/ML	FROZEN	45 DAYS
VITAMIN B COMPLEX LIPO V		FROZEN	45 DAYS
VITAMIN B6	110 MG/ML	FROZEN	45 DAYS
VITAMIN D3	100,000 IU/ML	ROOM TEMPERATURE	1 DAY


[redacted]
(702) 458-
9500
AMERICAN WELLNESS
PHARMACY
2775 S JONES BLVD #104
LAS VEGAS NV 89146
SHIP TO:
ELITE HEALTH IV
STORE IN
REFRIGERATOR
DATE THAWED
DISCARD AFTER 3 DAYS
607
[redacted]
160 CIE
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FILED
JUN 18 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **THOMAS SCHOTIK, RPH, Certificate of Registration No. 08312,** **Respondents.**	**CASE NOS. 23-063-PH-S** **23-063-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Thomas Schotik, RPh (Schotik), Certificate of Registration No. 08312, was a pharmacist registered with the Board, and Respondent American Wellness Pharmacy, Pharmacy License No. PH02705, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Schotik was employed as managing pharmacist by American Wellness Pharmacy at the time of the events alleged herein.

3. On or about November 16, 2023, Board staff inspected American Wellness Pharmacy's premises and operations and determined that the pharmacy was compounding drug products in violation of law.

4. American Wellness Pharmacy compounded and sold drug products using active ingredients that (1) do not have a United States Pharmacopoeia-National Formulary monograph;

(2) are not a part of an FDA approved drug product, or (3) are not authorized to be used in pharmacy compounding pursuant to 21 USC § 353a(b)(1) or the regulations adopted pursuant thereto. Specifically, the pharmacy is advertising and dispensing compounded injectable peptides, including, without limitation, BPC-157, CJC 1295, Dihexa, GHK-CU, GAC, Kisspeptin, MK-677, PT-141, Thymosin Alpha-1, and Thymosin Beta-4.

5. American Wellness Pharmacy compounded and sold high-risk sterile products with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD, including, without limitation:

A. Multiple vials of compounded semaglutide 1.2mg/ml #30mL were found refrigerated with a lot date of 11/3/2023 and expiration date of 12/18/2023 with "refrigerate" on the label, with no studies on file to support an extended BUD.

B. Myers cocktail 50mL vials for office use were found refrigerated with a lot batch date of 10/25/2023 and 45-day BUD listed on the vial, with no studies on file to support an extended BUD.

C. Glutathione 200mg/ml 10ml vials were found refrigerated with a lot batch date of 11/15/2023 and a 90-day BUD, with no documentation to support the extended BUD.

D. Testosterone cypionate 50mg/ml with a 60-day BUD at room temperature lacking a potency documentation to justify the BUD.

APPLICABLE LAW

6. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661-.690, *inclusive*, and related federal law, 21 U.S.C. § 353a, establishing national standards for compounding medications.

7. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

8. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

9. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

10. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including, without limitation, maintenance of standards of purity of the pharmaceutical stock and recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1), NAC 639.510 and/or NAC 639.702.

11. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

COUNT ONE

Violations of Law – Drug Compounding

12. American Wellness Pharmacy's personnel violated NAC 639.67019, NAC 639.67067, NAC 639.67071 and/or NAC 639.757 and related provisions of 21 U.S.C. § 353a as alleged in paragraphs 3-5 herein.

13. As the managing pharmacist of American Wellness Pharmacy at the time of the violations alleged herein, Schotik is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1), NAC 639.510 and/or NAC 639.702.

14. As the pharmacy/pharmacy owner at which the violations alleged herein occurred, American Wellness Pharmacy is responsible for those violations, including all errors and omissions of the pharmacy personnel, and subject to discipline pursuant to pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

COUNT TWO

Unprofessional Conduct – Drug Compounding

15. By the acts alleged herein, Schotik and other personnel of American Wellness Pharmacy engaged in unprofessional conduct as defined in NAC 639.945(1)((i). Schotik is therefore subject to discipline pursuant to NRS 639.210(4), and American Wellness Pharmacy is therefore subject to discipline pursuant to NAC 639.945(2) and 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses and certificates of registration of these Respondents.

Signed this 18th day of June 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THOMAS SCHOTIK, RPH,** **Certificate of Registration No. 08312,** **Respondent.**	**Case No. 23-063-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

THOMAS SCHOTIK, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THOMAS SCHOTIK, RPH,** **Certificate of Registration No. 08312,** **Respondent.**	**Case No. 23-063-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 1st day of JULY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of June 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

American Wellness Pharmacy
2755 S. Jones Blvd Ste 100A
Las Vegas, NV 89146

Thomas Schotik, RPH
[redacted] Sean Darin Circle
Las Vegas, NV 89146

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

FILED
JUL 19 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THOMAS SCHOTIK, RPH,** **Certificate of Registration No. 08312,** **Respondent.**	**Case No. 23-063-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

Paragraph 3:
-The facts of the inspection are not disputed. I do deny that the Pharmacy was compounding medications in violation of the law.

Paragraph 4:
-All of the category 2 peptides were removed from our formulary and not advertised or promoted. Also a statement to the Board of Pharmacy was generated to this effect. (See attachment A)
-All of the peptides used in the compounding of medications have a valid certificate of analysis on file (see attachment A)

Paragraph 5:
-All of the lots that were indicated were isolated and destroyed. Following which a comprehensive list of all beyond use dates
with testing was generated (see attachment A)

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I, Thomas Schotik as acting PIC for American Wellness Pharmacy have always done my best to comply with all of the requests and promptings from the Board. Upon being made aware of something that needed to be dealt with, corrective action was swiftly taken to amend the situation. All of the products in question were immediately destroyed. All of our beyond use dates were reviewed and corrected. I believe that we are currently in full compliance with the regulations.

I will always do everything in my power to make any and all corrections given to me from the Board.

As of 07/22/2024 I shall no longer be the pharmacist in charge at American Wellness Pharmacy. (SEE ATTACHMENT B)

Please take this into consideration before taking away my livelihood.

Thomas Schotik Rph

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 17 th day of JULY, 2024.

RPh

THOMAS SCHOTIK, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **THOMAS SCHOTIK, RPH, Certificate of Registration No. 08312,** **Respondents.**	**CASE NOS. 23-063-PH-S** **23-063-RPH-S** **STIPULATION AND ORDER [SCHOTIK ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Thomas Schotik, RPh, Certificate of Registration No. 08312, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about June 18, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about July 19, 2024, Respondent filed an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. American Wellness Pharmacy, Pharmacy License No. PH02705, compounded and sold drug products using active ingredients that (1) do not have a United States Pharmacopoeia-National Formulary monograph; (2) are not a part of an FDA approved drug product, or (3) are not authorized to be used in pharmacy compounding pursuant to 21 USC § 353a(b)(1) or the regulations adopted pursuant thereto;

B. American Wellness Pharmacy compounded and sold high-risk sterile products with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD;

C. American Wellness Pharmacy's personnel violated NAC 639.67019, NAC 639.67067, NAC 639.67071 and/or NAC 639.757 and related provisions of 21 U.S.C. § 353a;

D. As the managing pharmacist of American Wellness Pharmacy at the time of the violations, Schotik is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1), NAC 639.510 and/or NAC 639.702; and

E. Schotik engaged in unprofessional conduct as defined in NAC 639.945(1)((i) and is therefore subject to discipline pursuant to NRS 639.210(4).

7. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Thomas Schotik, RPh, Certificate of Registration No. 08312, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Schotik shall pay a fine of Two Thousand Dollars ($2000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024; and

B. Pursuant to NRS 622.400, Schotik shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024; and

C. Schotik shall complete two (2) extra hours of continuing education (CE) on compounding, in addition to the CE hours he must otherwise complete to maintain licensure. Respondent shall provide certificates demonstrating that he completed those additional CEs by December 1, 2024.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024. Respondent will appear in person at the meeting to answer questions from the Board Members

and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 12th **day of** AUGUST **2024**

THOMAS SCHOTIK, RPH
Certificate of Registration No. 08312

Signed this ___ day of _____ 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Thomas Schotik, RPh, Certificate of Registration No. 08312, in Case No. 23-063-RPH-N, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2024.

_____

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5N

FILED
MAR 22 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID LANZKOWSKY, MD,** **Certificate of Registration No. CS06509, and** **WILLIAM BAUMGARTL, MD,** **Certificate of Registration No. CS19427,** **Respondents.**	**Case Nos. 23-106-CS-A-S** **23-106-CS-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent David Lanzkowsky, MD (Lanzkowsky), held a controlled substance registration, Certificate of Registration No. CS06509, and Respondent William Baumgartl, MD (Baumgartl), held a controlled substance registration, Certificate of Registration No. CS19427, both issued by the Board.

FACTUAL ALLEGATIONS

2. Lanzkowsky and Baumgartl are engaged in practice at Centennial Medical Group, located at 4454 N. Decatur Blvd. in Las Vegas, Nevada.

3. From December 27, 2022, to April 4, 2023, Lanzkowsky regularly permitted medical assistant Laura Barraza (Barraza) to use Lanzkowsky's credentials to issue electronic prescriptions for controlled substances.

4. From February 27, 2023, to April 4, 2023, Lanzkowsky and Baumgartl regularly permitted Barraza to use Lanzkowsky's credentials to issue electronic prescriptions for controlled substances for patients of Baumgartl, with whom Lanzkowsky had not established a bona fide therapeutic relationship, before Lanzkowsky had examined the patients, and for whom Lanzkowsky had neither diagnosed nor determined that a controlled substance was medically necessary.

APPLICABLE LAW

5. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession, to a patient with whom the practitioner has established a bona fide therapeutic relationship. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a); NRS 639.2813(1).

6. An electronic prescription for a controlled substance must be issued in compliance with 21 CFR § 1311.100, NRS 453.385, NRS 639.23535 and NAC 639.7105(2), and a practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person, and must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102.

7. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(1)(a).

8. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

9. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

10. Prescribing a drug to any patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n)(2) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that renders registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE
Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(Respondent Lanzkowsky ONLY)

14. By permitting Barraza to use his credentials and act under his authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraphs 3-4 herein, Lanzkowsky violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR § 1306.04(a), 21 CFR § 1311.100 and/or 21 CFR § 1311.102, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(Respondent Lanzkowsky ONLY)

15. By permitting Barraza to use his credentials and act under his authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraphs 3-4 herein, Lanzkowsky violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT THREE

Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(Respondent Baumgartl ONLY)

16. By using Lanzkowsky's credentials and acting under his authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraph 4 herein, Baumgartl violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report a violation of 21 CFR § 1311.100 and/or 21 CFR § 1311.102, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

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COUNT FOUR

Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(Respondent Baumgartl ONLY)

17. By using Lanzkowsky's credentials and acting under his authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraph 4 herein, Baumgartl violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report a violation of NRS 453.385, NRS 639.23535, NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT FIVE

Unprofessional Conduct – Party to Fraudulent or Deceitful Practice or Transaction

18. By engaging in the unauthorized use of Lanzkowsky's credentials and authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraphs 3-4 herein, Lanzkowsky and Baumgartl were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and each is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SIX

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

19. By engaging in the unauthorized use of Lanzkowsky's credentials and authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraphs 3-4 herein, Lanzkowsky and Baumgartl have each performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and each is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and NRS 639.210(4).

COUNT SEVEN

Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship (Respondent Lanzkowsky ONLY)

20. By fraudulently issuing electronic prescriptions for controlled substances to patients with whom he did not have a bona fide therapeutic relationship as alleged in Paragraph 4 herein, Lanzkowsky engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(n)(2), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT

Commission of Acts that Render Registration Inconsistent with the Public Interest

21. By their actions as alleged herein, Lanzkowsky and Baumgartl have each committed acts that render his registration inconsistent with the public interest, and each is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these respondents.

DATED this 22nd day of March 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID LANZKOWSKY, MD,** **Certificate of Registration No. CS06509,** **Respondent.**	**Case No. 23-106-CS-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID LANZKOWSKY, MD,** **Certificate of Registration No. CS06509,** **Respondent.**	**Case No. 23-106-CS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

DAVID LANZKOWSKY, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of March 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

David Lanzkowsky, MD
[redacted]N Decatur Blvd.
Las Vegas, NV 89130

William Baumgartl, MD
[redacted]N Decatur Blvd.
Las Vegas, NV 89130

William Baumgartl, MD
[redacted]W Horizon Ridge Pkwy
Henderson, NV 89052

William Baumgartl, MD
[redacted]Smoke Ranch Rd #[redacted]
Las Vegas, NV Nevada 89128

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID LANZKOWSKY, MD,** **Certificate of Registration No. CS06509, and** **WILLIAM BAUMGARTL, MD,** **Certificate of Registration No. CS19427**, **Respondents.**	**Case Nos. 23-106-CS-A-S** **23-106-CS-B-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent David Lanzkowsky, MD (Lanzkowsky), Certificate of Registration No. CS06509, and Respondent William Baumgartl (Baumgartl), MD, Certificate of Registration No. CS19427, by and through counsel, Tara A. Davidoff, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about March 22, 2024, Respondents were served with the Notice of Intended Action and Accusation on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about April 15, 2024, Respondents jointly filed an Answer and Notice of Defense to the Accusation.

3. On or about July 18, 2024, Respondents were served with the First Amended Notice of Intended Action and Accusation (First Amended Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

4. Respondents are fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to them pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Lanzkowsky has failed to comply with the provisions of this Stipulation, Lanzkowsky hereby knowingly and voluntarily waive his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. The allegation in Paragraph 4 of the First Amended Accusation is withdrawn and all related causes of action against Baumgartl in Case No. 23-106-CS-B-S, as set forth in Counts 3, 4, 5, 6 and 8, Paragraphs 16, 17, 18, 19 and 21 of the First Amended Accusation, are hereby DISMISSED pursuant to NRS 622A.320(4).

8. The causes of action against Lanzkowsky set forth in Counts 5, 6 and 7, Paragraphs 18, 19 and 20 of the First Amended Accusation, in Case No. 23-106-CS-A-S are hereby DISMISSED pursuant to NRS 622A.320(4).

9. The remaining causes of action against Lanzkowsky based upon the allegation in Paragraph 3 and set forth in Counts 1, 2 and 8, Paragraphs 14, 15 and 21 of the First Amended Accusation, in Case No. 23-106-CS-A-S stand, although Lanzkowsky does not admit to the violations alleged therein, *to wit,* that by permitting medical assistant Barraza to use his credentials and act under his authority to issue electronic prescriptions for controlled substances, Lanzkowsky violated 21 U.S.C. **§** 822(a)(2), 21 U.S.C. **§** 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR

§ 1306.04(a), 21 CFR § 1311.100, 21 CFR § 1311.102, NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and committed acts that render registration inconsistent with the public interest.

10. Those violations are pled with particularity in the First Amended Accusation and are grounds for action pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210, NRS 639.23916(3)(b) and/or NRS 639.255.

11. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent David Lanzkowsky, MD, Certificate of Registration No. CS06509, stipulate to the following penalties in Case No. 23106-CS-A-S:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Lanzkowsky shall pay a fine of Five Thousand Dollars ($5000.00) for the violations by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by October 1, 2024; and

B. Pursuant to NRS 622.400, Lanzkowsky shall pay One Thousand Dollars ($1000.00) to partially reimburse the Board for recoverable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by October 1, 2024.

12. Any failure by Lanzkowsky to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Lanzkowsky to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order Lanzkowsky, the Board

may impose additional discipline upon Lanzkowsky consistent with the provisions of NRS Chapters 453 and 639.

13. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024. Respondents and/or counsel will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.

14. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

15. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that the prosecution shall take such further action as necessary to dismiss all charges against Baumgartl in Case No. 23-106-CS-B-S and notice a full hearing before the Board at a later date on the merits of the charges against Lanzkowsky in Case No. 23-106-CS-A-S. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

16. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the First Amended Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents have fully considered the charges and allegations contained in the *First Amended Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2024

DAVID LANZKOWSKY, MD
Certificate of Registration No. CS06509

Signed this ___ day of _____ 2024

WILLIAM BAUMGARTL, MD
Certificate of Registration No. CS19427

APPROVED AS TO FORM AND CONTENT
this ___ day of _____ 2024

TARA A. DAVIDOFF, ESQ.
Counsel for Respondents

Signed this ___ day of _____ 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent David Lanzkowsky, MD, Certificate of Registration No. CS06509, in Case No. 23-106-CS-A-S, and Respondent William Baumgartl, MD, Certificate of Registration No. CS19427, in Case No. 23-106-CS-B-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID LANZKOWSKY, MD,** **Certificate of Registration No. CS06509, and** **WILLIAM BAUMGARTL, MD,** **Certificate of Registration No. CS19427,** **Respondents.**	**Case Nos. 23-106-CS-A-S** **23-106-CS-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent David Lanzkowsky, MD (Lanzkowsky), held a controlled substance registration, Certificate of Registration No. CS06509, and Respondent William Baumgartl, MD (Baumgartl), held a controlled substance registration, Certificate of Registration No. CS19427, both issued by the Board.

FACTUAL ALLEGATIONS

2. Lanzkowsky and Baumgartl are engaged in practice at Centennial Medical Group, located at 4454 N. Decatur Blvd. in Las Vegas, Nevada.

3. From December 27, 2022, to April 4, 2023, Lanzkowsky regularly permitted medical assistant Laura Barraza (Barraza) to use Lanzkowsky's credentials to issue electronic prescriptions for controlled substances.

4. From February 27, 2023, to April 4, 2023, Lanzkowsky and Baumgartl regularly permitted Barraza to use Lanzkowsky's credentials to issue electronic prescriptions for controlled substances for patients of Baumgartl, with whom Lanzkowsky had not established a bona fide therapeutic relationship, before Lanzkowsky had examined the patients, and for whom Lanzkowsky had neither diagnosed nor determined that a controlled substance was medically necessary.

APPLICABLE LAW

5. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession, to a patient with whom the practitioner has established a bona fide therapeutic relationship. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a); NRS 639.2813(1).

6. An electronic prescription for a controlled substance must be issued in compliance with 21 CFR § 1311.100, NRS 453.385, NRS 639.23535 and NAC 639.7105(2), and a practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person, and must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102.

7. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

8. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

9. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

10. Prescribing a drug to any patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n)(2) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that renders registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE
Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(Respondent Lanzkowsky ONLY)

14. By permitting Barraza to use his credentials and act under his authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraphs 3-4 herein, Lanzkowsky violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR § 1306.04(a), 21 CFR § 1311.100 and/or 21 CFR § 1311.102, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(Respondent Lanzkowsky ONLY)

15. By permitting Barraza to use his credentials and act under his authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraphs 3-4 herein, Lanzkowsky violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT THREE

Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(Respondent Baumgartl ONLY)

16. By using Lanzkowsky's credentials and acting under his authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraph 4 herein, Baumgartl violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report a violation of 21 CFR § 1311.100 and/or 21 CFR § 1311.102, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

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COUNT FOUR

Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(Respondent Baumgartl ONLY)

17. By using Lanzkowsky's credentials and acting under his authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraph 4 herein, Baumgartl violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report a violation of NRS 453.385, NRS 639.23535, NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT FIVE

Unprofessional Conduct – Party to Fraudulent or Deceitful Practice or Transaction

18. By engaging in the unauthorized use of Lanzkowsky's credentials and authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraphs 3-4 herein, Lanzkowsky and Baumgartl were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and each is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SIX

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

19. By engaging in the unauthorized use of Lanzkowsky's credentials and authority to fraudulently issue electronic prescriptions for controlled substances, as alleged in Paragraphs 3-4 herein, Lanzkowsky and Baumgartl have each performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and each is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and NRS 639.210(4).

COUNT SEVEN

Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship (Respondent Lanzkowsky ONLY)

20. By fraudulently issuing electronic prescriptions for controlled substances to patients with whom he did not have a bona fide therapeutic relationship as alleged in Paragraph 4 herein, Lanzkowsky engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(n)(2), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT

Commission of Acts that Render Registration Inconsistent with the Public Interest

21. By their actions as alleged herein, Lanzkowsky and Baumgartl have each committed acts that render his registration inconsistent with the public interest, and each is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these respondents.

DATED this 22nd day of March 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WILLIAM BAUMGARTL, MD,** **Certificate of Registration No. CS19427,** **Respondent.**	**Case No. 23-106-CS-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of May 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WILLIAM BAUMGARTL, MD,** **Certificate of Registration No. CS19427,** **Respondent.**	**Case No. 23-106-CS-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

WILLIAM BAUMGARTL, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of March 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

David Lanzkowsky, MD
[redacted]N Decatur Blvd.
Las Vegas, NV 89130

William Baumgartl, MD
[redacted]N Decatur Blvd.
Las Vegas, NV 89130

William Baumgartl, MD
[redacted]W Horizon Ridge Pkwy
Henderson, NV 89052

William Baumgartl, MD
[redacted]Smoke Ranch Rd #[redacted]
Las Vegas, NV Nevada 89128

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID LANZKOWSKY, MD,** **Certificate of Registration No. CS06509, and** **WILLIAM BAUMGARTL, MD,** **Certificate of Registration No. CS19427**, **Respondents.**	**Case Nos. 23-106-CS-A-S** **23-106-CS-B-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent David Lanzkowsky, MD (Lanzkowsky), Certificate of Registration No. CS06509, and Respondent William Baumgartl (Baumgartl), MD, Certificate of Registration No. CS19427, by and through counsel, Tara A. Davidoff, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about March 22, 2024, Respondents were served with the Notice of Intended Action and Accusation on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about April 15, 2024, Respondents jointly filed an Answer and Notice of Defense to the Accusation.

3. On or about July 18, 2024, Respondents were served with the First Amended Notice of Intended Action and Accusation (First Amended Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

4. Respondents are fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to them pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Lanzkowsky has failed to comply with the provisions of this Stipulation, Lanzkowsky hereby knowingly and voluntarily waive his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. The allegation in Paragraph 4 of the First Amended Accusation is withdrawn and all related causes of action against Baumgartl in Case No. 23-106-CS-B-S, as set forth in Counts 3, 4, 5, 6 and 8, Paragraphs 16, 17, 18, 19 and 21 of the First Amended Accusation, are hereby DISMISSED pursuant to NRS 622A.320(4).

8. The causes of action against Lanzkowsky set forth in Counts 5, 6 and 7, Paragraphs 18, 19 and 20 of the First Amended Accusation, in Case No. 23-106-CS-A-S are hereby DISMISSED pursuant to NRS 622A.320(4).

9. The remaining causes of action against Lanzkowsky based upon the allegation in Paragraph 3 and set forth in Counts 1, 2 and 8, Paragraphs 14, 15 and 21 of the First Amended Accusation, in Case No. 23-106-CS-A-S stand, although Lanzkowsky does not admit to the violations alleged therein, *to wit,* that by permitting medical assistant Barraza to use his credentials and act under his authority to issue electronic prescriptions for controlled substances, Lanzkowsky violated 21 U.S.C. **§** 822(a)(2), 21 U.S.C. **§** 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR

§ 1306.04(a), 21 CFR § 1311.100, 21 CFR § 1311.102, NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and committed acts that render registration inconsistent with the public interest.

10. Those violations are pled with particularity in the First Amended Accusation and are grounds for action pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210, NRS 639.23916(3)(b) and/or NRS 639.255.

11. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent David Lanzkowsky, MD, Certificate of Registration No. CS06509, stipulate to the following penalties in Case No. 23106-CS-A-S:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Lanzkowsky shall pay a fine of Five Thousand Dollars ($5000.00) for the violations by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by October 1, 2024; and

B. Pursuant to NRS 622.400, Lanzkowsky shall pay One Thousand Dollars ($1000.00) to partially reimburse the Board for recoverable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by October 1, 2024.

12. Any failure by Lanzkowsky to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Lanzkowsky to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order Lanzkowsky, the Board

may impose additional discipline upon Lanzkowsky consistent with the provisions of NRS Chapters 453 and 639.

13. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024. Respondents and/or counsel will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.

14. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

15. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that the prosecution shall take such further action as necessary to dismiss all charges against Baumgartl in Case No. 23-106-CS-B-S and notice a full hearing before the Board at a later date on the merits of the charges against Lanzkowsky in Case No. 23-106-CS-A-S. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

16. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the First Amended Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents have fully considered the charges and allegations contained in the *First Amended Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2024

DAVID LANZKOWSKY, MD
Certificate of Registration No. CS06509

Signed this ___ day of _____ 2024

WILLIAM BAUMGARTL, MD
Certificate of Registration No. CS19427

APPROVED AS TO FORM AND CONTENT
this ___ day of _____ 2024

TARA A. DAVIDOFF, ESQ.
Counsel for Respondents

Signed this ___ day of _____ 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent David Lanzkowsky, MD, Certificate of Registration No. CS06509, in Case No. 23-106-CS-A-S, and Respondent William Baumgartl, MD, Certificate of Registration No. CS19427, in Case No. 23-106-CS-B-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ROBERT FEINGOLD, MD,** **Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741, PD27479,** **Respondent.**	**CASE NO. 23-118-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Robert Feingold, MD, held controlled substance registrations, Certificate Nos. CS15741, CS18837, and CS28864, and dispensing practitioner registrations, Certificate Nos. PD15741, and PD27479, all issued by the Board.

FACTUAL ALLEGATIONS

2. On or about December 20, 2018, an annual Board inspection of Respondent's practice at Medical Weight Loss & Wellness Center, Inc. dba Advanced Medical Weight Loss & Wellness Center (Advanced Medical), located at 1450 W. Horizon Parkway, Suite B313 in Henderson, revealed that Respondent permitted unlicensed individuals to have independent access by key to the medication storage containing controlled substances and dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.

3. On or about December 29, 2021, a Board investigation at Advanced Medical revealed that Respondent permitted medical technician A.D. to have independent access by key

to the medication storage containing controlled substances and dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.

4. On or about February 1, 2022, a Board investigation at Advanced Medical revealed that Respondent continued to permit unlicensed medical assistants to have independent access by key to the medication storage containing controlled substances and dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.

5. On March 23, 2023, a Board investigation at Advanced Medical revealed that Respondent continued to permit unlicensed medical assistants to have independent access by key to the medication storage containing controlled substances and dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.

6. Respondent permitted persons not licensed as practitioners in Nevada, including, without limitation, Advanced Medical owner Claudia Baker, to act under his authority to operate Advanced Medical, to provide on-site medical treatment to patients, and to purchase, access, store, possess, administer, furnish and/or dispense controlled substances, dangerous drugs and hypodermic devices, including, without limitation, administering various injections of vitamins, glutathione, and amino blends, to patients with whom Respondent had not established a bona fide therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a prescription drug was medically necessary.

7. In June 2019, purchase orders and invoices from supplier Modern Medical reveal that Advanced Medical obtained 1000 tablets of alprazolam 0.5 mg under Respondent's credentials that were not accounted for in Advanced Medical's inventory in July 2019, nor were there any records showing the dispensing of alprazolam from Advanced Medical.

8. Advanced Medical's purchase orders/invoices indicated the purchases and deliveries of the following medications:

- Finasteride 1 mg tablets, quantity.90, on or about March 4, 2019, quantity 180, on June 28, 2019, and quantity 180 on August 19, 2019.
- Sildenafil citrate 100 mg, quantity 200 on May 1, 2019 and quantity 200 on August 19, 2019.
- Tretinoin cream 0.025% 45 gm on June 6, 2019, January 9, 2020, February 13, 2020, June 25, 2020, October 6, 2020, December 17, 2020, May 6, 2021, September 28, 2021, and January 13, 2022.

However, Advanced Medical maintained no inventory or dispensing records accounting for these medications.

9. Records evidence that Advanced Medical staff shipped controlled substances to out-of-state patients, including, without limitation, phentermine mailed to J.G. in San Antonio, TX on multiple occasions, and phendimetrazine mailed to J.C. in St. George, UT on multiple occasions.

10. Advanced Medical's dispensing logs substantiate that medications were dispensed when Respondent was not present at the facility, including, without limitation:

- hCG dispensed to patient C.B. on August 27, 2021;
- hCG dispensed to patient L.S. on September 10, 2021;
- phentermine lollipops dispensed to patient C.L. on September 24, 2021;
- hCG dispensed to patient J.D. on October 11, 2021;
- hCG dispensed to patients S.K. and S. R. on October 11, 2021; and
- phentermine lollipops dispensed to patient T.C. on November 5, 2021.

11. From June 2019 to January 2022, Respondent regularly prescribed controlled substances and dangerous drugs, including, without limitation, alprazolam, finasteride, sildenafil citrate, tretinoin cream, phentermine, hCG, sermorelin and ipamorelin, to patients with whom Respondent had not established a bona fide therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a prescription drug was medically necessary.

12. Respondent dispensed controlled substances and dangerous drugs ordered on patient-specific prescriptions to other patients, including, without limitation, hCG, phentermine lollipops, sermorelin and ipamorelin. For example: Records from Hallandale Pharmacy document the following prescriptions for hCG filled on October 21, 2021: Rx#2302889 for patient L.P; Rx#2305158 for patient B.S.; and Rx#2302886 for patient M.R. There is no record of these patients receiving these medications; however, Advanced Medical's dispensing logs document numerous other patients being dispensed hCG. Hallandale Pharmacy records also document the following prescriptions for phentermine lollipops filled on October 21, 2021: Rx#2302894 for patient C.E.; Rx#230902 for patient B.S.; Rx#2305996 for patient D.I.; and Rx#2305991 for patient A.T. There is no record of phentermine lollipops dispensed to these particular patients after the dates of the prescriptions; however, Advanced Medical's dispensing records document phentermine lollipops dispensed to other patients, including J.F., S.A., J.P., Y.M., and C.L.

13. Respondent failed to maintain accurate records of controlled substances dispensed. Prescription Monitoring Program (PMP) database prescriber activity reports document the following prescriptions dated September 15, 2022, which were not substantiated by Advanced Medical's dispensing records:

Rx#108741 - 1000 phentermine 37.5 mg tablets for a 7-day supply to patient K.B.

Rx#108739 - 1000 phentermine 37.5 mg tablets for an 84-day supply to patient L.H.

Rx#108736 - 1000 phentermine 37.5 mg tablets for a 7-day supply to patient D.M.

14. Respondent failed to review PMP patient utilization reports for a majority of his patients for whom he prescribed and/or dispensed controlled substances at Advanced Medical. From January 1, 2019, to January 1, 2022, Respondent's PMP patient request history report reveals a total of 26 inquiries for 20 unique patients; however, during that timeframe Respondent prescribed/dispensed 3,580 prescriptions for 816 unique patients. Respondent reviewed the PMP for less than 3% of all of his patients.

15. From September 1, 2022, to May 23, 2023, PMP patient utilization reports were not reviewed for most patients at Advanced Medical for whom Respondent prescribed and dispensed the controlled substance phentermine.

16. Respondent failed to query and review for accuracy his MyRx prescriber activity report as required at least once every 6 months.

APPLICABLE LAW

17. No person may possess, administer, furnish, prescribe or dispense a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR §§ 1306.03-1306.05; NRS 453.226(1); NRS 453.232; NRS 453.321(1)(a); NRS 453.377; NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.23505; NAC 639.742.

18. No person may possess, administer, furnish, prescribe or dispense a dangerous drug except as authorized by law. NRS 454.213(1); NRS 454.215(3); NRS 454.221; NRS 454.311; NRS 454.316; NRS 454.321; NRS 454.356; NRS 639.100(1); NRS 639.235(1); NRS 639.23505; NAC 639.742.

19. No person may possess, administer furnish, prescribe or dispense a hypodermic device except as authorized by law. NRS 454.480; NRS 454.510; NRS 454.530.

20. A practitioner may prescribe a controlled substance for a specific patient in conformance with 21 CFR §§ 1306.04-1306.05, NRS 639.2353 and NAC 453.440. A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients. 21 CFR §§ 1306.04(b); NRS 639.268(1)(a); NAC 453.430(1).

21. A practitioner may prescribe a dangerous drug for a specific patient in conformance with NRS 454.223 and NRS 639.2353.

22. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.331(1) (d) and (i); NRS 639.281(1); NRS 639.2813(1).

23. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

24. It is a felony offense to falsify a prescription for a dangerous drug. NRS 454.311(1).

25. All controlled substances and dangerous drugs in the possession of a practitioner must be kept in a locked storage area with access restricted to authorized persons. 21 CFR § 1301.71; NAC 453.400; NAC 453.410(1)(d); NAC 639.742(3)(c); NAC 639.745(1)(c).

26. A dispensing practitioner shall ensure, without limitation, that all drugs are ordered by the dispensing practitioner, all drugs are accounted and received by the dispensing practitioner, no prescription is dispensed unless the dispensing practitioner is on-site at the facility, and all drugs are dispensed only to the patient personally at the facility. NAC 453.410; NAC 639.742.

27. A dispensing practitioner shall keep and maintain complete, accurate and readily retrievable records accounting for all controlled substances and dangerous drugs. 21 U.S.C. § 842(a)(5), 21 CFR § 1304.04 21 CFR § 1304.21; NRS 453.246; NRS 453.251; NRS 453.326(1)(a); NRS 454.286; NAC 453.410(1); NAC 639.745(1) and (3)).

28. A prescribing practitioner shall only issue a controlled substance prescription after review of a patient's utilization report in the PMP database in conformance with NRS 639.23507.

29. A practitioner dispensing a controlled substance shall, not later than the next business day, report the dispensed prescription to the PMP database. NRS 453.163.

30. A practitioner shall review for accuracy his or her prescriber activity in the PMP database at least once every 6 months. NRS 453.164(7).

31. A dispensing practitioner allowing any person to perform any act in violation of NAC 639.742-.7445, inclusive, is subject to discipline relating to his or her registration. NAC 639.7445.

32. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

33. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

34. Aiding or abetting a person not licensed to practice in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

35. Prescribing or dispensing a drug to any patient with whom the prescribing or dispensing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and (o) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

36. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

37. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

38. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has

committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of Federal Controlled Substances Act – Issuing Fraudulent Controlled Substance Prescriptions

39. By fraudulently issuing controlled substance prescriptions as alleged in paragraphs 11 and 12 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), CFR § 1306.04(a) and (b), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Law – Issuing Fraudulent Controlled Substance Prescriptions

40. By fraudulently issuing controlled substance prescriptions as alleged in paragraphs 11 and 12 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (d) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1), NRS 639.2353, NAC 453.430(1) and/or NAC 453.440 and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE

Violations of State Law – Issuing Fraudulent Prescriptions for Dangerous Drugs

41. By fraudulently issuing prescriptions for dangerous drugs as alleged in paragraph 12 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213(3), NRS 454.221, NRS 454.223, NRS 454.301, NRS 454.311(1), NRS 454.316(2), NRS 639.2353, and/or NRS 639.268(1)(a), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT FOUR

Violation of State Law – Unlawful Operation of Advanced Medical

42. By permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Advanced Medical, to provide on-site medical treatment to patients, and to purchase, access, store, possess, administer, furnish and/or dispense controlled substances, dangerous drugs and hypodermic devices to patients with whom Respondent had not established a bona fide therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a prescription drug was medically necessary as alleged in paragraphs 6 and 11, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.377, NRS 453.381(1), NRS 454.213(1), NRS 454.215(3); NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 454.480, NRS 454.510, NRS 454.530, NRS 639.100(1), NRS 639.235(1), NRS 639.23505, NAC 453.410 and/or NAC 639.742, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.7445 and/or NRS 639.210(12).

COUNT FIVE

Violation of State Law – Additional Dispensing Practitioner Violations

43. By failing to ensure that no prescription is dispensed unless the dispensing practitioner is on-site at the facility and that all drugs are dispensed only to the patient personally at the facility, as alleged in paragraphs 9 and 10, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 453.410 and/or NAC 639.742, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.7445 and/or NRS 639.210(12).

COUNT SIX

Violations of Federal and State Law - Failure to Maintain Security of Controlled Substances and Dangerous Drugs

44. By permitting persons not licensed as practitioners in Nevada to have unrestricted access to the inventory of controlled substances and dangerous at Advanced Medical as alleged

in paragraphs 2-6 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1301.71, NAC 453.400, NAC 453.410(1)(d), NAC 639.742(3)(c) and/or NAC 639.745(1)(c), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

COUNT SEVEN

Violations of Federal and State Law - Recordkeeping

45. By failing to keep and maintain complete, accurate and readily retrievable records accounting for all controlled substances and dangerous drugs as alleged in paragraphs 7, 8 and 13 herein, Respondent violated 21 U.S.C. § 842(a)(5), 21 CFR § 1304.04 21 CFR § 1304.21; NRS 453.246, NRS 453.251, NRS 453.326(1)(a), NRS 454.286, NAC 453.410(1) and/or NAC 639.745(1) and (3), and is therefore subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

COUNT EIGHT

Violations of State Law - Prescription Monitoring Program

46. By failing to query the PMP database both prior to issuing and upon dispensing controlled substance prescriptions and to review for accuracy his MyRx prescriber activity as required, as alleged in paragraphs 14, 15 and 16 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.163, NRS 453.164(7) and NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT NINE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

47. By fraudulently prescribing and dispensing controlled substances and dangerous drugs as alleged in paragraphs 11 and 12 herein, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TEN

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

48. By his acts as alleged herein, Respondent has performed his duties as the holder of controlled substance and dispensing practitioner registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT ELEVEN

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice

49. By permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Advanced Medical, to provide on-site medical treatment to patients, and to purchase, access, store, possess, administer, furnish and/or dispense controlled substances, dangerous drugs and hypodermic devices to patients with whom Respondent had not established a bona fide therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a prescription drug was medically necessary as alleged in paragraphs 6 and 11, Respondent aided and abetted unlicensed practice and engaged in unprofessional conduct as defined in NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TWELVE

Unprofessional Conduct – Prescribing/Dispensing Without Bona Fide Therapeutic Relationship

50. By unlawfully prescribing and dispensing controlled substances and dangerous drugs to patients with whom he did not have a bona fide therapeutic relationship as alleged in paragraphs 6 and 11 herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(n) and (o), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT THIRTEEN

Commission of Acts that Render Registration Inconsistent with the Public Interest

51. By his acts as alleged herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of this Respondent.

Signed this 9th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ROBERT FEINGOLD, MD,** **Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741, PD27479,** **Respondent.**	**CASE NO. 23-118-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, May 29, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of February 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ROBERT FEINGOLD, MD, CERTIFICATE OF REGISTRATION NOS. CS15741, CS18837, CS28864, PD15741, PD27479,** **Respondent.**	**CASE NO. 23-118-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ___ day of _____, 2024.

_____

ROBERT FEINGOLD, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 14th day of February, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Robert Feingold, MD
[redacted] S. Valley View #[redacted]
Las Vegas, NV 89102

Robert Feingold, MD
Medical Reducing Inc.
2466-C E Desert Inn Rd.
Las Vegas, NV 89121

Robert Feingold, MD
Advanced Medical Weight Loss
& Wellness Center, Inc.
1450 W. Horizon Ridge Parkway, Suite B-313
Las Vegas, NV 89102

SHIRLEY HUNTING
BOARD COORDINATOR

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FEB 27 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JASON DAZLEY, MD,** **Certificate of Registration No. CS25977, and** **JOSEPH PALUMBO, DO,** **Certificate of Registration No. CS26034,** **Respondents.**	**CASE NOS. 23-266-CS-A-S** **23-266-CS-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Jason Dazley, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS25977, and Respondent Joseph Palumbo, DO, held a Nevada controlled substance registration, Certificate of Registration No. CS26034, both issued by the Board.

FACTUAL ALLEGATIONS

2. Respondents operated and/or served as medical directors of Prime IV, located at 10595 W Discovery Drive in Las Vegas, Nevada, during the relevant times frames herein.

3. Respondents permitted registered nurses (RNs), paramedics, Advanced Emergency Medical Technicians (AEMTs) and/or Emergency Medical Technicians (EMTs) to independently access, possess and administer dangerous drugs to patients, specifically, to provide on-site medical treatment at Prive IV, including the administration of dangerous drugs through intravenous (IV) therapy and/or injections without direct practitioner supervision, and

without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary.

APPLICABLE LAW

4. No person may possess or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356; NRS 639.100(1).

5. A practitioner may give an RN limited authority to possess and administer dangerous drugs pursuant to NRS 454.213(1)(c), which states in relevant part:

> A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

6. An AEMT or a paramedic who holds an endorsement issued pursuant to NRS 450B.1975 may possess and administer dangerous drugs under the direct supervision of a local health officer or a designee of the local health officer pursuant to NRS 454.213(1)(g).

7. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

8. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

9. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

10. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

11. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of State Law - Unlawful Possession & Administration of Dangerous Drugs

12. By permitting RNs, paramedics, AEMTs and/or EMTs to independently access, possess and administer dangerous drugs, without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.221, NRS 454.316, NRS 454.316, NRS 454.321, NRS 454.356 and NRS 639.100(1), and are subject to discipline pursuant to NRS 639.210(12).

COUNT TWO

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

13. By permitting RNs, paramedics, AEMTs and/or EMTs to independently access, possess and administer dangerous drugs, without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for

whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary, Respondents performed their duties as the holders of controlled substance registrations in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in, or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and are subject to discipline pursuant to NRS 639.210(4).

COUNT THREE

Commission of Acts that Render Registration Inconsistent with the Public Interest

14. By permitting RNs, paramedics, AEMTs and/or EMTs to independently access, possess, store and administer dangerous drugs, without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these Respondents.

Signed this 21st day of February 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JASON DAZIEY, MD,** **Certificate of Registration No. CS25977,** **Respondent.**	**CASE NO. 23-266-CS-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, May 29, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JASON DAZIEY, MD,** **Certificate of Registration No. CS25977,** **Respondent.**	**CASE NO. 23-266-CS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

JASON DAZIEY, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of February, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Jason Dazley, MD
[redacted]N. Pecos Rd.
North Las Vegas, NV 89086

Jason Dazley, MD
[redacted]Sparrow Gull Ct.
North Las Vegas, NV 89032

Joseph Palumbo, DO
[redacted]E. Lake Mead Blvd.
North Las Vegas, NV 89030

Joseph Palumbo, DO
c/o Brendan Little, Esq.
50 Fountain Plaza, Ste. 1700
Buffalo, NY 14202

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

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OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JASON DAZLEY, MD,** **Certificate of Registration No. CS25977, and** **JOSEPH PALUMBO, DO,** **Certificate of Registration No. CS26034,** **Respondents.**	**CASE NOS. 23-266-CS-A-S** **23-266-CS-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Jason Dazley, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS25977, and Respondent Joseph Palumbo, DO, held a Nevada controlled substance registration, Certificate of Registration No. CS26034, both issued by the Board.

FACTUAL ALLEGATIONS

2. Respondents operated and/or served as medical directors of Prime IV, located at 10595 W Discovery Drive in Las Vegas, Nevada, during the relevant times frames herein.

3. Respondents permitted registered nurses (RNs), paramedics, Advanced Emergency Medical Technicians (AEMTs) and/or Emergency Medical Technicians (EMTs) to independently access, possess and administer dangerous drugs to patients, specifically, to provide on-site medical treatment at Prive IV, including the administration of dangerous drugs through intravenous (IV) therapy and/or injections without direct practitioner supervision, and

without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary.

APPLICABLE LAW

4. No person may possess or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356; NRS 639.100(1).

5. A practitioner may give an RN limited authority to possess and administer dangerous drugs pursuant to NRS 454.213(1)(c), which states in relevant part:

> A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

6. An AEMT or a paramedic who holds an endorsement issued pursuant to NRS 450B.1975 may possess and administer dangerous drugs under the direct supervision of a local health officer or a designee of the local health officer pursuant to NRS 454.213(1)(g).

7. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

8. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

9. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

10. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

11. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of State Law - Unlawful Possession & Administration of Dangerous Drugs

12. By permitting RNs, paramedics, AEMTs and/or EMTs to independently access, possess and administer dangerous drugs, without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.221, NRS 454.316, NRS 454.316, NRS 454.321, NRS 454.356 and NRS 639.100(1), and are subject to discipline pursuant to NRS 639.210(12).

COUNT TWO

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

13. By permitting RNs, paramedics, AEMTs and/or EMTs to independently access, possess and administer dangerous drugs, without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for

whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary, Respondents performed their duties as the holders of controlled substance registrations in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in, or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and are subject to discipline pursuant to NRS 639.210(4).

COUNT THREE

Commission of Acts that Render Registration Inconsistent with the Public Interest

14. By permitting RNs, paramedics, AEMTs and/or EMTs to independently access, possess, store and administer dangerous drugs, without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these Respondents.

Signed this 27th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOSEPH PALUMBO, DO,** **Certificate of Registration No. CS26034,** **Respondent.**	**CASE NO. 23-266-CS-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, May 29, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 27th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOSEPH PALUMBO, DO,** **Certificate of Registration No. CS26034,** **Respondent.**	**CASE NO. 23-266-CS-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

JOSEPH PALUMBO, DO

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of February, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Jason Dazley, MD
[redacted] N. Pecos Rd.
North Las Vegas, NV 89086

Jason Dazley, MD
[redacted] Sparrow Gull Ct.
North Las Vegas, NV 89032

Joseph Palumbo, DO
[redacted] E. Lake Mead Blvd.
North Las Vegas, NV 89030

Joseph Palumbo, DO
c/o Brendan Little, Esq.
50 Fountain Plaza, Ste. 1700
Buffalo, NY 14202

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

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FILED
APR 26 2024
NEVADA STATE BOARD OF PHARMACY

Aaron Bart Fricke, Esq.
Nevada Bar No.: 11129
SKLAR WILLIAMS PLLC
410 South Rampart Boulevard, Ste. 350
Las Vegas, Nevada 89145
Telephone: (702) 360-6000
Facsimile: (702) 360-0000
Email: africke@sklar-law.com

Attorney for Joseph Palumbo, DO

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. JOSEPH PALUMBO, DO, Certificate of Registration No., CS26034 Respondent.	CASE NO.: 23-266-CS-BS **ANSWER AND NOTICE OF DEFENSE**

With sincere respect for the Nevada States Board of Pharmacy ("Board"), Respondent above named, in answer to the Notice of Intended Action and Accusation ("Complaint") filed in the above-titled matter before the Board, declares that his objections to the Complaint as being incomplete or failing to state clearly the charges against him is hereby interposed on the following grounds:

1. Answering Paragraph 1, Respondent admits that the Nevada State Board of Pharmacy (Board) has jurisdiction over this matter, and that at the time of the events alleged herein, Respondent Joseph Palumbo, DO, held a Nevada controlled substance registration, Certificate of Registration No. CS26034, issued by the Board. As for the remaining allegations, Respondent is without sufficient knowledge or information upon which to form a belief as to the truth or falsity of the allegations set forth therein and upon that basis denies each and every allegation set forth therein.

2. Answering Paragraph 2, Respondent admits that, for limited and specific purposes, he served as one of at least two or more "medical directors" of Prime IV, located at 10595 W Discovery Drive in Las Vegas, Nevada, from November 11, 2022, to the date of the Complaint, February 27, 2024. As for the remaining allegations, Respondent is without sufficient

knowledge or information upon which to form a belief as to the truth or falsity of the allegations set forth therein and upon that basis denies each and every allegation set forth therein.

3. Answering Paragraph 3, Respondent asserts that these allegations are made without any reference to specific facts, and made against multiple individual licensees with different and apparently overlapping periods of, and differing professional involvement with, the unspecified events that have been placed, apparently, in question by these allegations. The allegations refer, apparently, to multiple, unspecified patients with whose care Respondent had no involvement whatsoever, and with respect to care rendered by persons and/or practitioners other than Respondent, and about which Respondent had no knowledge. This generic pleading makes it impossible for Respondent to understand the nature of the allegations against him, specifically, which makes formulating a defense impossible, violates Respondent's Sixth Amendment rights, and is an unconstitutionally vague method of pleading that fails to apprise the Respondent, with reasonable certainty, of the allegations against him and, thus, deprives him of the ability to prepare a defense. *See* Dutchess Bus. Servs., Inc. v. Nevada State Bd. of Pharmacy, 124 Nev. 701, 711, 191 P.3d 1159, 1166 (2008) ("Although proceedings before administrative agencies may be subject to more relaxed procedural and evidentiary rules, due process guarantees of fundamental fairness still apply . . . [the Board must] give notice to the defending party of the issues on which decision will turn and the factual material on which the agency relies for decision so that he may rebut it."); In re Ruffalo, 390 U.S. 544, 550-551 (1968) (state professional board disciplinary proceedings are "adversary proceedings of a quasi-criminal nature" so that adequate notice of the charges must be given); United States v. Nance, 533 F.2d 699, 701 (D.C. Cir. 1976). Accordingly, Respondent is without sufficient notice, knowledge and information upon which to form a belief as to the truth or falsity of the allegations set forth therein and upon that basis denies each and every allegation set forth therein.

4. Answering Paragraph 4, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient knowledge or information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

5. Answering Paragraph 5, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph

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may be construed as factual allegations, Respondent is without sufficient knowledge or information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

6. Answering Paragraph 6, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient knowledge or information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

7. Answering Paragraph 7, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient knowledge or information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

8. Answering Paragraph 8, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient knowledge or information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

9. Answering Paragraph 9, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient knowledge or information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

10. Answering Paragraph 10, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient knowledge or information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

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11. Answering Paragraph 11, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient knowledge or information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

COUNT ONE

Violation of State Law - Unlawful Possession & Administration of Dangerous Drugs

12. Answering Paragraph 12, Respondent incorporates his responses to the previous Paragraphs 1 through 11 by reference, as if they were fully set forth herein. The allegations contained in this paragraph are duplicitous, insofar as the Board has joined in a single count two or more distinct and separate offenses, and multiplicitous, insofar as the Board charges a single offense in multiple counts, making a specific response impossible. Gordon v. Eighth Judicial District Court, 112 Nev. 216, 228, 913 P.2d 240, 247-8 (1996); United States v. UCO Oil Co., 546 F.2d 833, 835 (9th Cir. 1976). Further, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient notice, knowledge and information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

COUNT TWO

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

13. Answering Paragraph 13, Respondent incorporates his responses to the previous Paragraphs 1 through 12 by reference, as if they were fully set forth herein. The allegations in this Paragraph 13 are duplicitous, insofar as the Board has joined in a single count two or more distinct and separate offenses, and multiplicitous, insofar as the Board charges a single offense in multiple counts, making a specific response impossible. Gordon v. Eighth Judicial District Court, 112 Nev. 216, 228, 913 P.2d 240, 247-8 (1996); United States v. UCO Oil Co., 546 F.2d 833, 835 (9th Cir. 1976). Further, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient notice, knowledge and information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

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COUNT THREE

Commission of Acts that Render Registration Inconsistent with the Public Interest

14. Answering Paragraph 14, Respondent incorporates his responses to the previous Paragraphs 1 through 13 by reference, as if they were fully set forth herein. The allegations in this Paragraph 14 are duplicitous, insofar as the Board has joined in a single count two or more distinct and separate offenses, and multiplicitous, insofar as the Board charges a single offense in multiple counts, making a specific response impossible. Gordon v. Eighth Judicial District Court, 112 Nev. 216, 228, 913 P.2d 240, 247-8 (1996); United States v. UCO Oil Co., 546 F.2d 833, 835 (9th Cir. 1976). Further, this paragraph calls for a legal conclusion and therefore Respondent need not respond to the allegations set forth therein. Nonetheless, out of an abundance of caution, Respondent states that to the extent any of the allegations in this paragraph may be construed as factual allegations, Respondent is without sufficient notice, knowledge and information to either admit or deny the allegations contained in this paragraph, and on this basis, denies each and every allegation set forth therein.

For the reasons set forth herein, and based on such objections to and admissions and denials of the allegations set forth herein, Respondent denies the allegations and respectfully requests that the Board take no action with respect to the Respondent.

DATED this 26 day of April, 2024.

SKLAR WILLIAMS PLLC

By _____
Aaron Bart Fricke, Esq.
Nevada Bar No.: 11129
410 South Rampart Boulevard
Las Vegas, Nevada 89145
Attorney for Joseph Palumbo, DO

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DocuSigned by:
Joseph Palumbo, DO
99C5153BCAA942E...
Joseph Palumbo, DO

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CERTIFICATE OF SERVICE

I hereby certify that I am an employee of SKLAR WILLIAMS PLLC, and that on this 26th day of April, 2024, I caused the foregoing **Answer and Notice of Defense** to be sent via email to the following electronic mail addresses below:

TeamBC@Pharmacy.nv.gov

bkandt@pharmacy.nv.gov

/s/ Amanda Brandon
Amanda Brandon
An employee of SKLAR WILLIAMS PLLC

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JASON DAZIEY, MD,** **Certificate of Registration No. CS25977, and** **JOSEPH PALUMBO, DO,** **Certificate of Registration No. CS26034,** **Respondents.**	**CASE NOS. 23-266-CS-A-S** **23-266-CS-B-S** **STIPULATION AND ORDER** **[RESPONDENT PALUMBO ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Joseph Palumbo, DO, Certificate of Registration No. CS26034, by and through counsel**,** Aaron Bart Fricke, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about February 27, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about April 26, 2024, Respondent filed an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent contests the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Respondent permitted registered nurses (RNs) to independently access, possess and administer dangerous drugs, without direct practitioner supervision, in violation of NRS 454.213 and NRS 639.100(1); and

B. By his actions Respondent has engaged in, or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945, and committed acts that render registration inconsistent with the public interest as defined in NRS 453.231(1)(e).

7. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.255.

8. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. Respondent Joseph Palumbo, DO, Certificate of Registration No. CS26034, is placed on probation pursuant to NRS 639.255(1)(b) for a period of one (1) year subject to the following conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a practitioner under NRS Chapters 453, 454 and 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Two Thousand Five Hundred Dollars ($2,500.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024;

C. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS26034 will be fully restored.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024. Respondent will appear at the meeting to answer questions from the Board Members and/or

Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2024

JOSEPH PALUMBO, DO
Certificate of Registration No. CS26034

Signed this ___ day of _____ 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of _____ 2024

AARON BART FRICKE, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Joseph Palumbo, DO, Certificate of Registration No. CS26034, in Case No. 23-266-B-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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FILED
MAR 22 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW DIKIN, DO,** **Certificate of Registration No. CS26423,** **Respondent.**	**CASE NO. 23-482-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Matthew Dikin, DO, held a Nevada controlled substance registration, Certificate of Registration No. CS26423, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about October 4, 2023, the Nevada State Board of Osteopathic Medicine (NSBOM) entered an order in Case No. OT2301003, summarily suspending Respondent's NSBOM License No. DO2227 to practice osteopathic medicine for cause on the basis that the health, safety of welfare of the public and any patient served by the Respondent was at risk of imminent or continued harm.

3. The suspension of Respondent's NSBOM License No. DO2227 operated as an immediate suspension of his Certificate of Registration No. CS26423 with the Board pursuant to NRS 639.2107.

4. The NSBOM Case No. OT2301003 was based in pertinent part on criminal charges initiated against Respondent in December 2020 and December 2022.

5. Respondent failed to disclose to the Board the 2020 criminal charges on his 2022 biennial renewal application for Certificate of Registration No. CS26423.

6. Respondent failed to disclose to the Board the suspension of his NSBOM License No. DO2227.

7. Respondent issued a controlled substance prescription in Nevada on October 23, 2023, prescription no. 474042, after the suspension of his Certificate of Registration No. CS26423.

8. From November 29, 2021 to November 29, 2023 Respondent issued thirty-seven controlled substance prescriptions in Nevada utilizing his U.S. Drug Enforcement Administration (DEA) Certificate of Registration No. BD5774042 for the State of Tennessee.

9. On or about December 5, 2023, the NSBOM entered an order in Case No. OT2301003, lifting the summary suspension of Respondent's NSBOM License No. DO2227 to practice osteopathic medicine; however, Respondent has failed to petition the Board for reinstatement of his Certificate of Registration No. CS26423 pursuant to NRS 639.2565.

APPLICABLE LAW

10. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

11. Each controlled substance prescription issued in Nevada must include the practitioner's DEA registration number for this State. 21 CFR § 1306.05(a); NRS 453.385; NAC 453.440(1)(k).

12. When an individual practitioner practices in more than one state, he or she must obtain a separate DEA registration for each state; a DEA registration based on a state license cannot authorize controlled substance prescribing outside that state. 21 CFR § 1301.12(b)(3); *see also* 71 Fed. Reg. 69478 (December 1, 2006).

13. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

14. It is unlawful for a person knowingly or intentionally to omit any material information from any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

15. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

16. The holder of any certificate, license or permit issued by the Board shall report to the Executive Secretary any administrative action taken against the holder by any professional licensing board or any state or federal agency not later than 30 days after the final disposition of the administrative action and provide any documentation of the administrative action requested by the Executive Secretary. NAC 639.229(1)(b).

17. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

18. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC

639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

19. The Board may suspend or revoke a controlled substance registration upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of Federal Controlled Substances Act

20. By issuing controlled substance prescription no. 474042 after the suspension of his Certificate of Registration No. CS26423, and by issuing thirty-seven controlled substance prescriptions in Nevada utilizing his DEA Certificate of Registration No. BD5774042 for Tennessee, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 CFR § 1306.03(a)(1), 21 CFR § 1306.05(a) and/or 21 CFR § 1301.12(b)(3), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Controlled Substances Act

21. By issuing controlled substance prescription no. 474042 after the suspension of his Certificate of Registration No. CS26423, and by issuing thirty-seven controlled substance prescriptions in Nevada utilizing his DEA Certificate of Registration No. BD5774042 for Tennessee, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.385, NRS 639.100(1), NRS 639.235(1), NRS 639.2813(1) and/or NAC 453.440(1)(k), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE
Furnishing False Material Information to Board

22. By failing to disclose to the Board the 2020 criminal charges on his 2022 biennial renewal application for Certificate of Registration No. CS26423, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT FOUR
Failure to Disclose Suspension of Nevada Osteopathic Medicine License

23. By failing to disclose to the Board the suspension of his NSBOM License No. DO2227, Respondent violated NAC 639.229(1)(b), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT FIVE
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

24. By failing to disclose to the Board the 2020 criminal charges on his 2022 biennial renewal application for Certificate of Registration No. CS26423, by failing to disclose to the Board the suspension of his NSBOM License No. DO2227, by issuing controlled substance prescription no. 474042 after the suspension of his Certificate of Registration No. CS26423, and by issuing thirty-seven controlled substance prescriptions in Nevada utilizing his DEA Certificate of Registration No. BD5774042 for Tennessee, Respondent has performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

COUNT SIX
Unprofessional Conduct – Prescribing on Suspended Registration

25. By issuing controlled substance prescriptions after the suspension of his Certificate of Registration No. CS26423, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SEVEN

Commission of Acts that Render Registration Inconsistent with the Public Interest

26. By failing to disclose to the Board the 2020 criminal charges on his 2022 biennial renewal application for Certificate of Registration No. CS26423, by failing to disclose to the Board the suspension of his NSBOM License No. DO2227, by issuing controlled substance prescription no. 474042 after the suspension of his Certificate of Registration No. CS26423, and by issuing thirty-seven controlled substance prescriptions in Nevada utilizing his DEA Certificate of Registration No. BD5774042 for Tennessee, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 22nd day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW DIKIN, DO,** **Certificate of Registration No. CS26423,** **Respondent.**	**CASE NO. 23-482-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW DIKIN, DO,** **Certificate of Registration No. CS26423,** **Respondent.**	**CASE NO. 23-482-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

MATTHEW DIKIN, DO

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of March 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Matthew Dikin, DO
[redacted]W. Sunset Rd.
Las Vegas, NV 89148

DARLENE NASES
BOARD COORDINATOR

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMAZON PHARMACY #002,** **Pharmacy License No. PH03988,** **Respondent.**	**CASE NO. 24-102-PH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Amazon Pharmacy #002, Pharmacy License No. PH03988 (Amazon), located in Phoenix, AZ, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. On or about August 20, 2019, Dr. R.F. submitted an oral prescription order to Amazon for patient J.S. for Depakote DR 250 mg tablets, subsequently designated as prescription no. 64229826. Patient J.S. was on a course of medication for Depakote ER that had previously been dispensed by Amazon.

3. On or about August 28, 2019, Amazon pharmaceutical technician Russell Dube, who is not registered with the Board, contacted the prescribing practitioner's office requesting clarification on prescription no. 64229826 and was advised that patient J.S. should continue to receive Depakote ER, and that it was never the prescribing practitioner's intention to change the prescription from Depakote ER to Depakote DR.

4. On or about August 28, 2019, Amazon pharmacist Danielle Richard, who is not registered with the Board, performed pharmacist verification (for accuracy and DUR) on prescription no. 64229826.

5. On or about September 16, 2019, the prescribing practitioner's office contacted Amazon and was informed by pharmaceutical technician Danielle James, who is not registered with the Board, that prescription no. 64229826 had not yet been dispensed to the patient.

6. On or about October 1, 2019, prescription no. 64229826 was finally dispensed by Amazon pharmacist Andrew Vo, Certificate of Registration No. 21573, to patient J.S., causing the patient, who suffers from acute bipolar disorder, to go without his medication for more than thirty days.

COUNT ONE

Failure to Timely Dispense Prescription/Unprofessional Conduct

7. Unprofessional conduct includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i). Amazon personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i) when they failed to timely dispense prescription no. 64229826 to patient J.S., which is a basis for discipline pursuant NRS 639.210(4).

8. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

9. As the pharmacy/pharmacy owner at which the unprofessional conduct alleged herein occurred, Amazon is responsible the unprofessional conduct, including all errors and omissions of Amazon personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

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COUNT TWO

Violation of State Law - Unauthorized Activity by Pharmaceutical Technician

10. A pharmaceutical technician under the direct supervision of a pharmacist may request authorization to refill a prescription from the prescribing practitioner but may not perform any action requiring a judgmental decision regarding the interpretation of a prescription or consult with a prescribing practitioner or the authorized agent thereof. NAC 639.245(2)(g) and (4)(a); NAC 639.700(4). Amazon pharmaceutical technician Russell Dube violated NAC 639.245(4)(a) and NAC 639.700(4) when he contacted the prescribing practitioner's office requesting clarification on prescription no. 64229826.

11. As the pharmacy/pharmacy owner at which the unprofessional conduct alleged herein occurred, Amazon is responsible the unprofessional conduct, including all errors and omissions of pharmaceutical technician Russell Dube, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of this Respondent.

Signed this 18th day of June 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMAZON PHARMACY #002,** **Pharmacy License No. PH03988,** **Respondent.**	**CASE NO. 24-102-PH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 1st day of JUNE 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMAZON PHARMACY #002,** **Pharmacy License No. PH03988,** **Respondent.**	**Case No. 24-102-PH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR AMAZON PHARMACY #002

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of June 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Amazon Pharmacy #002 c/o
Susan Brichler Trujillo, Esq.
Quarles & Brady LLP
One Renaissance Square, Two North Central Avenue, Suite 300
Pheonix, AZ 85004-2322

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMAZON PHARMACY #002,** **Pharmacy License No. PH03988,** **Respondent.**	**CASE NO. 24-102-PH-O** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Amazon Pharmacy #002 (Amazon), Pharmacy License No. PH03988, by and through counsel, Susan Brichler Trujillo, Esq., and Roger Morris, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. On or about June 18, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing. Respondent is entering this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be

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accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Amazon does not admit to the violations alleged in the Accusation, *to wit,* that:

A. Amazon personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i) when they failed to timely dispense prescription no. 64229826 to patient J.S., which is a basis for discipline pursuant NRS 639.210(4);

B. Amazon pharmaceutical technician Russell Dube violated NAC 639.245(4)(a) and NAC 639.700(4) when he contacted the prescribing practitioner's office requesting clarification on prescription no. 64229826; and

C. As the pharmacy/pharmacy owner at which the alleged unprofessional conduct occurred, Amazon is responsible the unprofessional conduct, including all errors and omissions of Amazon personnel, including pharmaceutical technician Russell Dube, pursuant to NRS 639.230(5), NAC 639.260, NAC 639.702 and/or NAC 639.945(3).

6. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Amazon Pharmacy #002, Pharmacy License No. PH03988, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Three Thousand Dollars ($3,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024; and

B. Pursuant to NRS 622.400, Respondent shall pay Two Thousand Dollars ($2,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by

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the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024. Respondent will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

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Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 12 day of August 2024

Signed by:
Hannah McClellan
D0308748C90E439...

AMAZON PHARMACY #002
Pharmacy License No. PH03988

Signed this ___ day of _____ 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 12 day of August 2024

SUSAN BRICHLER TRUJILLO, ESQ.
ROGER MORRIS, ESQ.
Counsel for Respondent

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Amazon Pharmacy #002, Pharmacy License No. PH03988, in Case No. 24-102-PH-O, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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FILED
SEP 28 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, M.D.,** **Certificate of Registration No. CS10935,** **Respondent.**	**Case No. 19-013-CS-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a first amended notice of intended action under NRS 233B.127(3) and a first amended accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over Respondent Matthew Okeke, M.D. (Respondent), because Respondent, at the time of the violations alleged herein, held a Nevada controlled substance registration, Certificate of Registration No. CS10935.

2. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice psychiatry in Nevada. During the time periods discussed herein, Respondent was a "practitioner" as that term is defined at NRS 453.126.

FACTUAL ALLEGATIONS

3. Between February 28, 2017, and November 21, 2018, Respondent maintained a psychiatric practice in Las Vegas, Nevada. During that time frame, while engaged at various times in overseas travel, Respondent issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances. These included prescriptions for alprazolam, clonazepam, diazepam, lacosamide, pregabalin, lisdexamfetamine, and buprenorphine.

4. Respondent was located outside of the United States during the periods from: 1) February 26 to March 11, 2017; 2) September 27 to October 2, 2017; 3) June 30 to July 17, 2018; and 4) November 9 to November 23, 2018.

5. While engaged in overseas travel as alleged above, Respondent employed the following methods of issuing prescriptions for controlled substances: 1) Respondent pre-signed certain of the prescriptions and supplied then to persons under his supervision or control for subsequent distribution to consumers; 2) Respondent authorized or directed one or more persons under his supervision or control to issue prescriptions to consumers by affixing Respondent's signature to those prescriptions via a rubber stamp imprinted with Respondent's signature; and 3) Respondent authorized or directed one or more persons under his supervision or control to telephonically issue prescriptions for consumers using Respondent's name and controlled substances registration number.

6. During the periods described herein, Respondent intentionally failed to maintain patient treatment charts and/or records from which a person could reasonably determine whether Respondent had a bona fide therapeutic relationship with the persons to whom prescriptions for controlled substances were issued under Respondent's name and controlled substances registration number.

7. Respondent caused, directed, or permitted one or more persons under his supervision or control to issue prescriptions for controlled substances even though such person(s) were not licensed or registered under state or federal law to prescribe controlled substances. Respondent knew or should have known that such person(s) were not licensed or registered under state or federal law to prescribe controlled substances.

8. On or about March 9, 2020, the Nevada State Board of Medical Examiners disciplined Respondent for malpractice and for failure to maintain proper medical records.

9. On or about September 7, 2022, Respondent entered a guilty plea pursuant to a plea agreement of committing the offense of intentional failure to maintain adequate records, a gross misdemeanor violation of NRS 422.510(1).

10. On or about September 7, 2022, Discovery Mind Center Ltd. (Discovery Mind Center), a Nevada limited-liability company, entered a guilty plea pursuant to a plea agreement of submitting false claims to defraud Medicaid, a felony violation of NRS 422.540; and of using the identifying information of an older person for unlawful purposes, a felony violation of NRS 205.463.

11. At the time of the offenses described in paragraph 10 above, Respondent owned, controlled, and/or managed Discovery Mind Center. Respondent entered guilty pleas on behalf of Discovery Mind Center.

12. On or about December 8, 2022, the Nevada State Board of Medical Examiners disciplined Respondent for failure to maintain proper medical records.

13. On or about January 17, 2023, Respondent and Discovery Mind Center were sentenced for the criminal offenses described in paragraph 10 above. Discovery Mind Center was ordered to pay $330,000 in restitution, and Respondent was sentenced to probation and ordered to pay $300,000 in costs and penalties.

14. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was convicted pursuant to a plea agreement of one count of submitting false claims: Medicaid fraud, a category D felony in violation of NRS 422.540(1)(a) and NRS 422.540(2)(a), and one count of obtaining and using personal identifying information of an older person for unlawful purposes, a category D felony in violation of NRS 205.463(1) and NRS 205.463(3)(a).

15. At the time of the offenses described in paragraph 14 above, Respondent owned, controlled, and/or managed Matthew Okeke, M.D., Ltd., a Nevada limited-liability company. Respondent entered guilty pleas on behalf of the company.

16. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was sentenced for the offenses described in paragraph 14 above. The company was ordered to pay a fine of $100,000, among other fees and assessments.

17. Respondent was charged individually with the offenses described in paragraphs 9, 10, and 14 above. However, Respondent entered into plea agreements whereby he avoided individual convictions for all offenses except the gross misdemeanor offense described in paragraph 9 above.

18. On or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. The application specifically directed Respondent to disclose any charges, arrests, or convictions. Respondent disclosed the

conviction described in paragraph 9 above, referring to it as a "misdemeanor for record keeping," but he did not disclose the individual charges and/or arrests related to the felony fraud charges mentioned in paragraphs 10 and 14 above.

APPLICABLE LAW

19. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. *See* NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. *See* NRS 453.056.

20. Every practitioner who prescribes controlled substances in Nevada must secure and maintain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who fails to secure and maintain such a registration is subject to criminal and/or civil penalties for prescribing controlled substances without a registration. *See* NRS 453.232; NRS 453.553; NRS 453.5531.

21. In addition to any criminal or civil penalties that may apply, the Board may revoke or suspend the existing registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

22. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner: 1) performs, without the required registration, any task or operation for which registration is required; 2) performs his or her duties in an incompetent, unskillful, or negligent manner; 3) performs or engages in any fraudulent or deceitful transaction; or, 4) prescribes a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship. *See* NAC 639.945(1)(h)-(o).

23. Additionally, the Board may revoke or suspend the registration of any practitioner who has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to controlled substances, *see* NRS 639.210(11), or who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, *see* NRS 639.210(12).

24. Further, the Board may revoke or suspend the registration of any practitioner who has been convicted of a crime involving moral turpitude, dishonesty or corruption. *See* NRS 639.210(7)(c).

25. Finally, the Board may revoke or suspend the registration of any practitioner who "[h]as willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of [NRS chapter 639]." *See* NRS 639.210(9).

26. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon such practitioner. The fine may not exceed $10,000 for each offense. *See* NRS 639.255(1)(f) and (3).

COUNT ONE

Failure to Comply with Federal Registration Requirements

27. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribed controlled substances in Nevada without their having obtained a registration from the Drug Enforcement Division of the U.S. Department of Justice. This constitutes a violation of federal law relating to controlled substances. *See* 21 U.S.C. 822(a)(2); 21 C.F.R. § 1306.03(a)(1). It also constitutes a violation of NRS 639.210(11), an offense for which the Board may impose administrative discipline.

COUNT TWO

Failure to Comply with State Registration Requirements

28. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada without their having obtained a registration from the Board. This violates state law relating to controlled substances. *See* NRS 453.321(1); NRS 453.226. It also constitutes a violation of NRS 639.210(12), an offense for which the Board may impose administrative discipline.

COUNT THREE
Participating in Deceitful Transactions

29. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada.

30. Respondent engaged in the conduct described herein as part of a scheme to bill Medicaid for services that Respondent did not provide. In this regard, Respondent used prescriptions to falsely document patient visits that never occurred.

31. By causing prescriptions to be issued in the manner described herein, Respondent engaged in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(h).

COUNT FOUR
Issuing Pre-signed Prescriptions

32. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada by supplying patients with written prescriptions that Respondent had signed or stamped in advance of his overseas travel.

33. By causing prescriptions to be issued in the manner described herein, Respondent violated NRS 639.2353 by issuing pre-signed prescriptions. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 639.210(12). Through his conduct, Respondent has potentially subjected other persons to administrative discipline. *See* NAC 639.295(15). (a physician assistant is subject to discipline for supplying patients with pre-signed prescriptions).

COUNT FIVE
Issuing Prescriptions from Unauthorized Locations

34. Between May 18, 2022, and January 22, 2023, while located outside the United States, Respondent caused prescriptions for controlled substances to be issued in his name and under his controlled substances registration number.

35. By engaging in the conduct described herein, Respondent prescribed controlled substances from locations other than his office and/or a location properly registered with the Board. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 453.226; NRS 639.210(12); NAC 453.130(3).

COUNT SIX

Performing Duties in an Incompetent, Unskillful, or Negligent Manner

36. Respondent failed to maintain patient charts and records from which the Board and/or a member of the Board's staff could reasonably ascertain whether Respondent maintained bona fide therapeutic relationships with the persons to whom prescriptions for controlled substances were issued between May 18, 2022, and January 22, 2023. Pursuant to NRS 453.246 and NAC 639.945(1)(o), Respondent had a legal duty to maintain such records.

37. By failing to maintain records as required by NRS 453.246 and NAC 639.945(1)(o), Respondent violated state law relating to controlled substances and/or performed his duties in an incompetent, unskillful and/or negligent manner. This is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12); NAC 639.945(1)(i).

38. By subjecting persons under his supervision or control to potential disciplinary action, Respondent performed his duties in an incompetent, unskillful and/or negligent manner. This too is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN

Failure to Establish Bona Fide Patient Relationships

39. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances for persons whom Respondent identified as his patients. Respondent did not establish bona fide therapeutic relationship with one or more of these ostensible patients.

40. Respondent's conduct as described above constitutes unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(o).

COUNT EIGHT
Conviction of Crime Involving Dishonesty

41. As described above, Respondent was convicted of intentional failure to maintain adequate records, a gross misdemeanor.

42. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, was directly related to a fraudulent billing scheme involving the Discovery Mind Center and Matthew Okeke, M.D., Ltd., both limited-liability companies under the ownership and control of Respondent.

43. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, amounted to a conviction for a crime involving dishonesty. The Board may impose administrative discipline based upon that conviction. *See* NRS 639.210(7)(c).

COUNT NINE
Willfully Making False Statements in Connection with Renewal Application

44. As alleged above, on or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. On the application, Respondent falsely represented that he had never been charged with or arrested for a criminal offense other than a misdemeanor offense related to record keeping. When he made this representation, Respondent had recently been charged with and/or arrested for multiple felony offenses related to a scheme to defraud Medicaid.

45. When he made the above false representation, Respondent knew that he had recently been charged with and/or arrested for multiple felony offenses related to a scheme to defraud Medicaid.

46. Respondent's false statement was material to the Board's determination whether to renew Respondent's certificate of registration to prescribe controlled substances.

47. Having willfully made a false representation as alleged above, Respondent is subject to discipline pursuant to NRS 639.210(9).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 26th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this First Amended Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, MD,** **Certificate of Registration No. CS10935,** **Respondent.**	**CASE NO. 19-013-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the First Amended Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the First Amended Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has rescheduled your hearing on this matter for Wednesday, December 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of September, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, MD,** **Certificate of Registration No. CS10935,** **Respondent.**	**CASE NO. 19-013-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

MATTHEW OKEKE, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of September 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Liborius Agwara, JD, PhD
Law Offices of Libo Agwara, LTD
2785 E. Desert Inn Road, Suite 280
Las Vegas, NV 89121

Matthew Okeke, MD
[redacted] S. Las Vegas Blvd., #[redacted]
Las Vegas, NV 89101

SHIRLEY HUNTING

FILED
JAN 17 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. MATTHEW OKEKE, M.D., Certificate of Registration No. CS10935, Respondent.	Case No. 19-013-CS-S FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

This matter came before the Nevada State Board of Pharmacy at its regularly scheduled meeting on Wednesday, January 17, 2024. Gregory L. Zunino, Senior General Counsel, prosecuted the case before the Board. Respondent Matthew Okeke, M.D., Certificate of Registration No. CS10935, failed to appear after being properly served notice of the time, date, and place of the hearing. Pursuant to NRS 622A.350(2) and NRS 638.244(2), the Board adopted, as its Findings of Fact and Conclusions of Law, the allegations, averments, and legal conclusions stated in the Notice of Intended Action and Accusation on file herein. Those allegations, averments, and legal conclusions are restated below with minor conforming changes, as appropriate, to reflect the Board's determination to impose professional discipline in this case.

FINDINGS OF FACT

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Matthew Okeke, M.D. (Respondent), because Respondent, at the time of the violations alleged herein, held a Nevada controlled substance registration, Certificate of Registration No. CS10935.

2. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice psychiatry in Nevada. During the time periods discussed herein, Respondent was a "practitioner" as that term is defined at NRS 453.126.

3. Between February 28, 2017, and November 21, 2018, Respondent maintained a psychiatric practice in Las Vegas, Nevada. During that time frame, while engaged at various times in overseas travel, Respondent issued or caused to be issued at least one hundred twenty (120)

prescriptions for controlled substances. These included prescriptions for alprazolam, clonazepam, diazepam, lacosamide, pregabalin, lisdexamfetamine, and buprenorphine.

4. Respondent was located outside of the United States during the periods from: 1) February 26 to March 11, 2017; 2) September 27 to October 2, 2017; 3) June 30 to July 17, 2018; and 4) November 9 to November 23, 2018.

5. While engaged in overseas travel as stated above, Respondent employed the following methods of issuing prescriptions for controlled substances: 1) Respondent pre-signed certain of the prescriptions and supplied then to persons under his supervision or control for subsequent distribution to consumers; 2) Respondent authorized or directed one or more persons under his supervision or control to issue prescriptions to consumers by affixing Respondent's signature to those prescriptions via a rubber stamp imprinted with Respondent's signature; and 3) Respondent authorized or directed one or more persons under his supervision or control to telephonically issue prescriptions for consumers using Respondent's name and controlled substances registration number.

6. During the periods described herein, Respondent intentionally failed to maintain patient treatment charts and/or records from which a person could reasonably determine whether Respondent had a bona fide therapeutic relationship with the persons to whom prescriptions for controlled substances were issued under Respondent's name and controlled substances registration number.

7. Respondent caused, directed, or permitted one or more persons under his supervision or control to issue prescriptions for controlled substances even though such person(s) were not licensed or registered under state or federal law to prescribe controlled substances. Respondent knew or should have known that such person(s) was not licensed or registered under state or federal law to prescribe controlled substances.

8. On or about March 9, 2020, the Nevada State Board of Medical Examiners disciplined Respondent for malpractice and for failure to maintain proper medical records.

9. On or about September 7, 2022, Respondent entered a guilty plea pursuant to a plea agreement of committing the offense of intentional failure to maintain adequate records, a gross misdemeanor violation of NRS 422.510(1).

10. On or about September 7, 2022, Discovery Mind Center Ltd. (Discovery Mind Center), a Nevada limited-liability company, entered a guilty plea pursuant to a plea agreement of submitting false claims to defraud Medicaid, a felony violation of NRS 422.540; and of using the identifying information of an older person for unlawful purposes, a felony violation of NRS 205.463.

11. At the time of the offenses described in paragraph 10 above, Respondent owned, controlled, and/or managed Discovery Mind Center. Respondent entered guilty pleas on behalf of Discovery Mind Center.

12. On or about December 8, 2022, the Nevada State Board of Medical Examiners disciplined Respondent for failure to maintain proper medical records.

13. On or about January 17, 2023, Respondent and Discovery Mind Center were sentenced for the criminal offenses described in paragraph 10 above. Discovery Mind Center was ordered to pay $330,000 in restitution, and Respondent was sentenced to probation and ordered to pay $300,000 in costs and penalties.

14. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was convicted pursuant to a plea agreement of one count of submitting false claims: Medicaid fraud, a category D felony in violation of NRS 422.540(1)(a) and NRS 422.540(2)(a), and one count of obtaining and using personal identifying information of an older person for unlawful purposes, a category D felony in violation of NRS 205.463(1) and NRS 205.463(3)(a).

15. At the time of the offenses described in paragraph 14 above, Respondent owned, controlled, and/or managed Matthew Okeke, M.D., Ltd., a Nevada limited-liability company. Respondent entered guilty pleas on behalf of the company.

16. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was sentenced for the offenses described in paragraph 14 above. The company was ordered to pay a fine of $100,000.00, among other fees and assessments.

17. Respondent was charged individually with the offenses described in paragraphs 9, 10, and 14 above. As noted above, Respondent entered into plea agreements whereby he avoided individual convictions for all offenses except the gross misdemeanor offense described in paragraph 9 above.

18. On or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. The application specifically directed Respondent to disclose any charges, arrests, or convictions. Respondent disclosed the conviction described in paragraph 9 above, referring to it as a "misdemeanor for record keeping," but he omitted to disclose the individual charges and/or arrests related to the more serious offenses described in paragraphs 10 and 14 above.

CONCLUSIONS OF LAW

19. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. *See* NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. *See* NRS 453.056.

20. Every practitioner who prescribes controlled substances in Nevada must secure and maintain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who fails to secure and maintain such a registration is subject to criminal and/or civil penalties for prescribing controlled substances without a registration. *See* NRS 453.232; NRS 453.553; NRS 453.5531.

21. In addition to any criminal or civil penalties that may apply, the Board may revoke or suspend the existing registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

22. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner: 1) performs, without the required registration, any task or operation for which

registration is required; 2) performs his or her duties in an incompetent, unskillful, or negligent manner; 3) performs or engages in any fraudulent or deceitful transaction; or, 4) prescribes a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship. *See* NAC 639.945(1)(h)-(o).

23. Additionally, the Board may revoke or suspend the registration of any practitioner who has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to controlled substances, *see* NRS 639.210(11), or who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, *see* NRS 639.210(12).

24. Further, the Board may revoke or suspend the registration of any practitioner who has been convicted of a crime involving moral turpitude, dishonesty or corruption. *See* NRS 639.210(7)(c).

25. Finally, the Board may revoke or suspend the registration of any practitioner who "[h]as willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of [NRS chapter 639]." *See* NRS 639.210(9).

26. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon such practitioner. The fine may not exceed $10,000 for each offense. *See* NRS 639.255(1)(f) and (3).

COUNT ONE

Failure to Comply with Federal Registration Requirements

27. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribed controlled substances in Nevada without their having obtained a registration from the Drug Enforcement Division of the U.S. Department of Justice. This constitutes a violation of federal law relating to controlled substances. *See* 21 U.S.C. 822(a)(2); 21 C.F.R. § 1306.03(a)(1). It also constitutes a violation of NRS 639.210(11), an offense for which the Board may impose administrative discipline.

COUNT TWO

Failure to Comply with State Registration Requirements

28. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada without their having obtained a registration from the Board. This violates state law relating to controlled substances. *See* NRS 453.321(1); NRS 453.226. It also constitutes a violation of NRS 639.210(12), an offense for which the Board may impose administrative discipline.

COUNT THREE

Participating in Deceitful Transactions

29. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada.

30. Respondent engaged in the conduct described herein as part of a scheme to bill Medicaid for services that Respondent did not provide. In this regard, Respondent used prescriptions to falsely document patient visits that never occurred.

31. By causing prescriptions to be issued in the manner described herein, Respondent engaged in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(h).

COUNT FOUR

Issuing Pre-signed Prescriptions

32. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada by supplying patients with written prescriptions that Respondent had signed or stamped in advance of his overseas travel.

33. By causing prescriptions to be issued in the manner described herein, Respondent violated NRS 639.2353 by issuing pre-signed prescriptions. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 639.210(12). Through his conduct,

Respondent has potentially subjected other persons to administrative discipline. *See* NAC 639.295(15). (a physician assistant is subject to discipline for supplying patients with pre-signed prescriptions).

COUNT FIVE

Issuing Prescriptions from Unauthorized Locations

34. Between May 18, 2022, and January 22, 2023, while located outside the United States, Respondent caused prescriptions for controlled substances to be issued in his name and under his controlled substances registration number.

35. By engaging in the conduct described herein, Respondent prescribed controlled substances from locations other than his office and/or a location properly registered with the Board. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 453.226; NRS 639.210(12); NAC 453.130(3).

COUNT SIX

Performing Duties in an Incompetent, Unskillful, or Negligent Manner

36. Respondent failed to maintain patient charts and records from which the Board and/or a member of the Board's staff could reasonably ascertain whether Respondent maintained bona fide therapeutic relationships with the persons to whom prescriptions for controlled substances were issued between May 18, 2022, and January 22, 2023. Pursuant to NRS 453.246 and NAC 639.945(1)(o), Respondent had a legal duty to maintain such records.

37. By failing to maintain records as required by NRS 453.246 and NAC 639.945(1)(o), Respondent violated state law relating to controlled substances and/or performed his duties in an incompetent, unskillful and/or negligent manner. This is a conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12); NAC 639.945(1)(i).

38. By subjecting persons under his supervision or control to potential disciplinary action, Respondent performed his duties in an incompetent, unskillful and/or negligent manner. This too is a conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN

Conviction of Crime Involving Dishonesty

39. As described herein, Respondent was convicted of a crime involving dishonesty. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, was directly related to a fraudulent billing scheme involving the Discovery Mind Center and Matthew Okeke, M.D., Ltd., both limited-liability companies under the ownership and control of Respondent. The Board may impose administrative discipline based upon that conviction because the underlying offense involved dishonesty. *See* NRS 639.210(7)(c).

COUNT EIGHT

Prescribing Controlled Substances Without a Bona Fide Patient Relationship

40. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances for persons whom Respondent identified as his patients. Respondent did not establish bona fide therapeutic relationship with one or more of these ostensible patients.

41. Respondent's conduct as described above constitutes unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(o).

ORDER

NOW, THEREFORE, based upon the above Findings of Fact and Conclusions of Law, the Board imposes upon Respondent Matthew Okeke, M.D., Certificate of Registration No. CS10935, the following professional discipline:

42. Respondent's Certificate of Registration No. CS10935 is hereby **REVOKED** pursuant to NRS 453.236 and NRS 453.241. Pursuant to NRS 622A.410(1) and NRS 639.257(1), Respondent may not petition the Board for reinstatement for a period of at least ten (10) years. Respondent may not prescribe controlled substances in the state of Nevada in any capacity unless the Board reinstates his certificate of registration.

43. Respondent shall pay an administrative fine in the amount of Two Thousand Five Hundred and No/100 Dollars ($2,500.00), payable to the State of Nevada, Office of the Treasurer.

44. Respondent shall reimburse the Board for its costs of investigation and prosecution in the amount of One Thousand Seven Hundred Fifty-Four and 68/100 Dollars ($1,754.68), payable to the Nevada State Board of Pharmacy.

45. This Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5) and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

46. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 17th day of January 2024.

Helen Park, President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Liborius Agwara, JD, PhD
Law Offices of Libo Agwara, LTD
2785 E. Desert Inn Road, Suite 280
Las Vegas, NV 89121

Matthew Okeke, MD
[redacted] S. Las Vegas Blvd., [redacted]
Las Vegas, NV 89101

Darlene Nases
DARLENE NASES

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, M.D.,** **Certificate of Registration No. CS10935,** **Respondent.**	**Case No. 19-013-CS-S** **ORDER VACATING DECISION**

Respondent Matthew Okeke, M.D. (Respondent), by and through counsel, Liborius Agwara, Esq., petitioned the Nevada State Board of Pharmacy (Board) to vacate its Findings of Fact, Conclusions of Law, and Order dated January 17, 2024 (Order). By issuance of the Order, the Board revoked Respondent's Certificate of Registration No. CS10935 after Respondent failed to appear for the scheduled hearing. Pursuant to NRS 622A.390, Respondent petitioned the Board to vacate the Order on the ground that Respondent was reasonably unaware of the hearing due to circumstances beyond his control. The Board, acting through its undersigned President pursuant to NRS 622A.390(4), found good cause to vacate the Order and proceed with disciplinary proceedings stemming from the First Amended Notice of Intended Action and Accusation on file herein.

NOW, THEREFORE, the Order is hereby VACATED, and the disciplinary charges currently pending against Respondent shall be heard at the Board's next available public meeting. Respondent understands and acknowledges that Respondent's Certificate of Registration No. CS10935 has been placed on inactive status pursuant to NAC 453.285(1). Accordingly, Respondent shall not prescribe or unlawfully possess controlled substances pending the final disposition of these disciplinary proceedings. This decision is effective immediately.

Entered this 6th day of March 2024.

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NEGAR SAFAVI, RPH,** **Certificate of Registration No. 18099,** **and,** **CVS PHARMACY # 6717,** **Pharmacy License No. PH01932,** **Respondents.**	**Case Nos. 20-133-PH-S** **20-133-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Negar Safavi ("Respondent Safavi"), because Respondent Safavi holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing her to engage in the practice of pharmacy in the state of Nevada.

2. The Board has personal jurisdiction over Respondent CVS Pharmacy #6717 ("Respondent CVS"), because Respondent CVS holds a license issued by the Board pursuant to NRS 639.230, authorizing Respondent CVS to operate a pharmacy located at 60 N. Valle Verde Drive in Henderson, Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because the violations alleged herein involve the practice of pharmacy at a pharmacy location operated by Respondent CVS in Henderson, Nevada.

FACTUAL ALLEGATIONS

4. In June 2020, Respondent Safavi was a registered pharmacist employed by Respondent CVS at its pharmacy on North Valle Verde Drive in Henderson, Nevada.

5. On or about June 24, 2020, while on duty at the pharmacy location on North Valle Verde Drive, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg.

6. The 14 tablets were dispensed pursuant to a prescription written by T.E.'s physician, who provided instructions for T.E. to take 1 tablet by mouth every 12 hours. Respondent CVS assigned prescription number 888727 to that order. A CVS pharmacist or pharmacy technician entered the relevant details about the prescription into the CVS computer system.

7. As of June 24, 2020, Respondent CVS had not previously filled a prescription for T.E. for Oxycodone. Accordingly, the CVS computer system alerted pharmacy staff that patient counseling was required by Nevada law before dispensing the drug.

8. T.E. unknowingly left the pharmacy with just 14 tablets even though T.E.'s physician had written the prescription for 56 tablets. When T.E. later discovered that she had not received the full supply of Oxycodone as prescribed by her physician, she complained to CVS pharmacy employees. T.E. later submitted a lengthy complaint to the Board in which she alleged, among other things, that someone had stolen her Oxycodone.

9. Respondent Safavi neglected to counsel T.E. before T.E. left the pharmacy on June 24, 2020, with 14 tablets instead of 56 tablets as prescribed.

10. Between June 24, 2020, and June 26, 2020, Respondent Safavi investigated T.E.'s complaints concerning the alleged theft of her Oxycodone. Having reviewed pharmacy records, Respondent Safavi determined that there had been no theft of T.E.'s Oxycodone. Respondent Safavi explained to T.E. and/or to T.E.'s physician that T.E. had received just 14 tablets, as opposed to 56 tablets, because T.E.'s insurance would not agree to pay for more than a 7-day supply.

11. T.E. insisted that her insurance would have paid for 56 tablets had pharmacy employees requested preauthorization to fill the full 28-day supply. Respondent Safavi and/or other CVS employees explained that the insurance company would not have processed a request for preauthorization until after she had received the initial 7-day supply. T.E. continued to demand a full 28-day supply of Oxycodone.

12. Between June 24, 2020, and 26, 2020, Respondent Safavi attempted to resolve T.E.'s complaints about having received a short supply of Oxycodone. Respondent Safavi states that she attempted to edit the entry in the CVS computer system for prescription number 88727, and to obtain preauthorization from T.E.'s insurance company. Ultimately, it was determined that T.E.'s insurance would not pay for a 28-day supply of Oxycodone.

13. According to Respondent Safavi, her edits to the data entry for prescription number 88727 were intended to reflect that the prescribed 28-day supply had been partially dispensed on June 24, 2020, and/or to reflect that T.E. would pay cash for the balance of the drug rather than use insurance.

14. Respondent Safavi states that she tried but was unable to edit the data entry for prescription number 88727 to reflect that the prescription had been partially and not fully dispensed. Consequently, the description of the prescribed drug, the dose, and the dosage remained in the system without amendment or modification.

15. Due to Respondent Safavi's edits and/or attempted edits as described above, the CVS computer system automatically prompted another CVS pharmacist, Todd Spears, to fill prescription number 88727 according to the prescription information that remained in the system. That information conformed to the prescription as originally written by T.E.'s physician, without any indication that the prescription had been partially dispensed on June 24, 2020.

16. On or about June 26, 2020, acting in reliance upon the information in the CVS computer system, Spears filled prescription number 88727 with a full 28-day supply of Oxycodone tablets. Spears placed the filled prescription in the pharmacy's waiting bin. Spears stated that he had not previously interacted with T.E. or been made aware of any issues with her prescription.

17. On or about July 24, 2020, T.E. picked up a full 28-day supply of Oxycodone tablets. According to T.E., a pharmacy employee handed her a bag without asking her to sign for the receipt of the contents or present photo identification. Respondent CVS was unable to produce a record of the July 24, 2020, transaction.

18. At no time between June 24, 2020, and July 24, 2020, did T.E.'s physician write her a second prescription for Oxycodone. According to Respondent Safavi, the CVS computer system did not generate a record of the transaction on July 24, 2020, because the system had already been programmed to reflect that prescription number 88727 was fully dispensed on June 24, 2020. As indicated above, Respondent Safavi was unable to modify or amend the applicable data entry.

19. As of October 16, 2020, Respondent CVS had not corrected pharmacy records to reflect that prescription number 88727 was only partially filled on June 24, 2020, and then filled a second time on July 24, 2020, with an excess number of Oxycodone 10 mg tablets.

APPLICABLE LAW

20. The Board may revoke or suspend the registration of any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4). Likewise, the Board may revoke or suspend the registration of any pharmacist who has violated any provision of Nevada law relating to prescription drugs. NRS 639.210(12). In lieu of revoking or suspending a pharmacist's registration, the Board may impose fines as a disciplinary measure. NRS 639.255; NAC 639.955.

21. A pharmacist's conduct is deemed unprofessional if the pharmacist fails to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling. NAC 639.945(1)(d). Additionally, a pharmacist's conduct is deemed unprofessional if the pharmacist performs his or her duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

22. Unless otherwise provided by law, a pharmacist must verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the

patient. Failure to provide appropriate counseling to the patient constitutes a violation of NRS 639.707(1). Pursuant to NRS 639.210(12), the Board may discipline a pharmacist who violates NRS 639.707(1).

23. Pursuant to NAC 639.910, a computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides a readily retrievable printed record of the information relating to a prescription or a patient which the pharmacy is required to maintain pursuant to state or federal law, including, without limitation, information relating to the original prescription or the refill or modification of that prescription.

24. Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy managers, and/or pharmacists are responsible for the acts and omissions of the pharmacy workers under their supervision and/or in their employ.

COUNT ONE
Failure to Counsel
(Respondents Safavi and CVS)

25. On or about June 24, 2020, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg. This was 42 fewer tablets than what had been prescribed by T.E.'s physician.

26. Respondent Safavi neglected to counsel T.E. before T.E. left the pharmacy with 14 tablets of Oxycodone.

27. Had Respondent Safavi properly counseled T.E., she would have alerted T.E. to the discrepancy between the number of tablets dispensed versus the number of tablets prescribed. This, in turn, would have alerted Respondent Safavi to correct the entry in the CVS computer system before it ostensibly became irreversible.

28. Respondent Safavi's conduct as alleged above violated NRS 639.707(1). Further, Respondent's conduct as alleged above was negligent. Accordingly, Respondent Safavi is subject to discipline pursuant to NRS 629.210(4), NRS 639.210(12), and NAC 639.945(1)(i).

29. As the owner/operator of the pharmacy at which Respondent Safavi was employed, Respondent CVS is responsible for Respondent Safavi's conduct as alleged above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

COUNT TWO
Failure to Follow Physician's Instructions
(Respondents Safavi and CVS)

30. On or about June 24, 2020, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg. This was 42 fewer tablets than what had been prescribed by T.E.'s physician.

31. Respondent Safavi did not obtain T.E.'s consent, nor the consent of T.E.'s physician, to deviate from the instructions on the prescription.

32. Having failed to obtain consent to deviate from the instructions on the prescription, Respondent Safavi failed to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling.

33. Having failed to obtain consent to deviate from the instructions on the prescription, Respondent Safavi performed her duties in a negligent manner.

34. Respondent Safavi's negligent conduct as alleged above was unprofessional. Accordingly, Respondent Safavi is subject to discipline pursuant to NRS 639.210(4) and NAC 639.945(1)(d) and (i).

35. As the owner/operator of the pharmacy at which Respondent Safavi was employed, Respondent CVS is liable for Respondent Safavi's' negligent conduct as described above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5) and NAC 639.945(2).

COUNT THREE
Failure to Follow Physician's Instructions
(Respondents Safavi and CVS)

36. On or about June 24, 2020, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg. This was 42 fewer tablets than what had been prescribed by T.E.'s physician.

37. Between June 24 and 26, 2020, Respondent Safavi attempted without success to edit pharmacy records to reflect that prescription number prescription number 88727 was partially and not fully dispensed on June 24, 2020. Although Respondent Safavi knew that her attempts to edit pharmacy records were unsuccessful, Respondent Safavi neglected to monitor the status of prescription number 88727.

38. As a result of Respondent Safavi's failure to monitor the status of prescription number 88727, another CVS pharmacist erroneously filled the prescription a second time by adding 56 Oxycodone tablets to the 14 tablets that had already been dispensed to T.E. This, in turn, caused Respondent CVS and/or its employees to dispense too many tablets to T.E, thus deviating from the instructions of the person writing, making, or ordering prescription number 88727 as to its filling or refilling.

39. Respondent Safavi's conduct as alleged above was negligent. Accordingly, she is subject to discipline for having engaged in unprofessional conduct. NRS 639.210(4); NAC 639.945(1)(d) and (i).

40. As the owner/operator of the pharmacy at which Respondent Safavi was employed, Respondent CVS is liable for Respondent Safavi's conduct as described above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5) and NAC 639.945(2).

COUNT FOUR
Failure to Maintain Accurate Records
(Respondent CVS)

41. On or about June 24, 2020, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg. This was 42 fewer tablets than what had been prescribed by T.E.'s physician.

42. On information and belief, Respondent CVS designed its computer system in such a way as to make it difficult if not impossible for Respondent Safavi to correct the history and status of prescription number 88727 as it appeared in pharmacy records.

43. As of October 16, 2020, Respondent CVS had not corrected pharmacy records to reflect that prescription number 88727 was only partially filled on June 24, 2020, and then filled a second time on July 24, 2020, with an excess number of Oxycodone 10 mg tablets.

44. Acting by and through its officers, employees, consultants, and/or independent contractors, Respondent CVS designed a computerized system that was incapable of providing a readily retrievable printed record of relevant information relating to prescription number 88727. Through this conduct, Respondent CVS violated NAC 639.910.

45. Based on the foregoing, Respondent CVS may be disciplined pursuant to NRS 639.210(12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Safavi and the pharmacy license of Respondent CVS.

DATED this 22 day of February 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NEGAR SAFAVI, RPH,** **Certificate Of Registration No. 18099,** **and,** **CVS Pharmacy # 6717** **License No. PH01932,** **Respondents.**	**Case Nos. 20-133-PH-S** **20-133-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, May 29, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 27th day of February 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NEGAR SAFAVI, RPH,** **Certificate Of Registration No. 18099,** **and,** **CVS Pharmacy # 6717** **License No. PH01932,** **Respondents.**	**Case Nos. 20-133-PH-S** **20-133-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY # 6717

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of February 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

CVS Pharmacy #6717
60 N Valle Verde Dr.
Henderson, NV 89074

Brian Convery, Esq.
200 Campus Drive, Suite 310
Florham Park, NJ 07932

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NEGAR SAFAVI, RPH,** **Certificate of Registration No. 18099,** **and,** **CVS PHARMACY #6717,** **Pharmacy License No. PH01932,** **Respondent.**	**Case No. 20-133-RPH-S** **20-133-PH-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its Senior General Counsel, Gregory L. Zunino, Respondent Negar Safavi ("Respondent Safavi"), and Respondent CVS Pharmacy #6717 ("Respondent CVS") hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Safavi and Respondent CVS (together "Respondents"), and this matter.

2. The Board's staff properly served each of Respondents with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondents agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.

4. Respondents acknowledge that they understand the terms of this Stipulation and Proposed Order ("Stipulation"), and they have executed it knowingly and voluntarily.

5. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondents under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative

procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that either of Respondents has failed to comply with the provisions of this Stipulation, Respondents hereby freely and voluntarily waive their rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Respondent Safavi admits that evidence exists, and that the Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One and Count Three of the Accusation. Although Respondent Safavi denies any direct, individual responsibility for the violation alleged in Count Three of the Accusation, Respondent Safavi acknowledges that pursuant to NAC 639.702, she is responsible for the violation because she was acting as managing pharmacist at the time of the violation and reasonably should have known of the acts and/or omissions of her subordinates. The parties further agree that Count Four of the Accusation does not apply to Respondent Safavi. Finally, the parties agree that Count Two of the Accusation arises from the same facts and circumstances as are alleged in Count One, such that Count Two is partially duplicative of Count One. Therefore, upon approval of this Stipulation by the Board, Count Two of the Accusation shall be dismissed with prejudice as to Respondent Safavi.

8. Respondent CVS admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One, Count Three, and Count Four of the Accusation. The parties agree that Count Two of the Accusation arises from the same facts and circumstances as are alleged in Count One, such that Count Two is partially duplicative of Count One. Therefore, upon approval of this Stipulation by the Board, Count Two of the Accusation shall be dismissed with prejudice as to Respondent CVS.

9. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent Safavi agree to the imposition of the following penalties:

A. Respondent Safavi shall pay an administrative fine of Five Hundred and No/100 Dollars ($500.00) as to each of the violations alleged in Count One and Count Three of the

Accusation, for a total administrative fine of One Thousand and 00/100 Dollars ($1,000.00). This sum shall be payable by *cashier's check, certified check, CVS company check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent Safavi shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

B. Respondent Safavi shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check, CVS company check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent Safavi shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

10. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent CVS agree to the imposition of the following penalties:

A. Respondent CVS shall pay an administrative fine of Five Hundred and No/100 Dollars ($500.00) as to each of the violations alleged in Count One, Count Three, and Count Four of the Accusation, for a total administrative fine of One Thousand Fine Hundred and 00/100 Dollars ($1,500.00). This sum shall be payable by *cashier's check, certified check, business check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent CVS shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

B. Respondent CVS shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check, business check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent CVS shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

11. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 20-133-RPH-S as to Respondent Safavi, and a full and final resolution of the Accusation in Case No. 20-133-PH-S as to Respondent CVS. However, failure by either Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing the noncompliant Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by that Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

12. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents fails to appear for the meeting.

13. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

14. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

15. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED: 8/20/24

Signed this ____ day of _____ 2024.

NEGAR SAFAVI

Signed this ____ day of _____2024.

GREGORY L. ZUNINO
Senior General Counsel

Signed this ___ day of _____2024

CVS PHARMACY # 6717

By: Pharmacist
Name: Negar Safavi
Title: Pharmacy Manager

DECISION AND ORDER

As to Respondent Negar Safavi and Respondent CVS Pharmacy #6717, in Case No. 20-133-RPH-S and Case No. 20-133-PH-S, respectively, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 4th day of September 2024.

Helen Park, President
Nevada State Board of Pharmacy

AGREED:

Signed this ____ day of _____ 2024.

NEGAR SAFAVI

Signed this 20th day of Aug 2024.

GREGORY L. ZUNINO
Senior General Counsel

Signed this 16th day of Aug 16, 2024 2024

CVS PHARMACY # 6717

By: _____
Name: Leigh Parenteau
Title: Sr. Manager, Pharmacy Regulatory Affairs

DECISION AND ORDER

As to Respondent Negar Safavi and Respondent CVS Pharmacy #6717, in Case No. 20-133-RPH-S and Case No. 20-133-PH-S, respectively, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 4th day of September 2024.

Helen Park, President
Nevada State Board of Pharmacy

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FILED
FEB 28 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

NEGAR SAFAVI, RPH,
Certificate of Registration No. 18099,

and,

CVS PHARMACY # 6717,
Pharmacy License No. PH01932,

Respondents.

Case Nos. 20-133-PH-S
20-133-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Negar Safavi ("Respondent Safavi"), because Respondent Safavi holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing her to engage in the practice of pharmacy in the state of Nevada.

2. The Board has personal jurisdiction over Respondent CVS Pharmacy #6717 ("Respondent CVS"), because Respondent CVS holds a license issued by the Board pursuant to NRS 639.230, authorizing Respondent CVS to operate a pharmacy located at 60 N. Valle Verde Drive in Henderson, Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because the violations alleged herein involve the practice of pharmacy at a pharmacy location operated by Respondent CVS in Henderson, Nevada.

FACTUAL ALLEGATIONS

4. In June 2020, Respondent Safavi was a registered pharmacist employed by Respondent CVS at its pharmacy on North Valle Verde Drive in Henderson, Nevada.

5. On or about June 24, 2020, while on duty at the pharmacy location on North Valle Verde Drive, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg.

6. The 14 tablets were dispensed pursuant to a prescription written by T.E.'s physician, who provided instructions for T.E. to take 1 tablet by mouth every 12 hours. Respondent CVS assigned prescription number 888727 to that order. A CVS pharmacist or pharmacy technician entered the relevant details about the prescription into the CVS computer system.

7. As of June 24, 2020, Respondent CVS had not previously filled a prescription for T.E. for Oxycodone. Accordingly, the CVS computer system alerted pharmacy staff that patient counseling was required by Nevada law before dispensing the drug.

8. T.E. unknowingly left the pharmacy with just 14 tablets even though T.E.'s physician had written the prescription for 56 tablets. When T.E. later discovered that she had not received the full supply of Oxycodone as prescribed by her physician, she complained to CVS pharmacy employees. T.E. later submitted a lengthy complaint to the Board in which she alleged, among other things, that someone had stolen her Oxycodone.

9. Respondent Safavi neglected to counsel T.E. before T.E. left the pharmacy on June 24, 2020, with 14 tablets instead of 56 tablets as prescribed.

10. Between June 24, 2020, and June 26, 2020, Respondent Safavi investigated T.E.'s complaints concerning the alleged theft of her Oxycodone. Having reviewed pharmacy records, Respondent Safavi determined that there had been no theft of T.E.'s Oxycodone. Respondent Safavi explained to T.E. and/or to T.E.'s physician that T.E. had received just 14 tablets, as opposed to 56 tablets, because T.E.'s insurance would not agree to pay for more than a 7-day supply.

11. T.E. insisted that her insurance would have paid for 56 tablets had pharmacy employees requested preauthorization to fill the full 28-day supply. Respondent Safavi and/or other CVS employees explained that the insurance company would not have processed a request for preauthorization until after she had received the initial 7-day supply. T.E. continued to demand a full 28-day supply of Oxycodone.

12. Between June 24, 2020, and 26, 2020, Respondent Safavi attempted to resolve T.E.'s complaints about having received a short supply of Oxycodone. Respondent Safavi states that she attempted to edit the entry in the CVS computer system for prescription number 88727, and to obtain preauthorization from T.E.'s insurance company. Ultimately, it was determined that T.E.'s insurance would not pay for a 28-day supply of Oxycodone.

13. According to Respondent Safavi, her edits to the data entry for prescription number 88727 were intended to reflect that the prescribed 28-day supply had been partially dispensed on June 24, 2020, and/or to reflect that T.E. would pay cash for the balance of the drug rather than use insurance.

14. Respondent Safavi states that she tried but was unable to edit the data entry for prescription number 88727 to reflect that the prescription had been partially and not fully dispensed. Consequently, the description of the prescribed drug, the dose, and the dosage remained in the system without amendment or modification.

15. Due to Respondent Safavi's edits and/or attempted edits as described above, the CVS computer system automatically prompted another CVS pharmacist, Todd Spears, to fill prescription number 88727 according to the prescription information that remained in the system. That information conformed to the prescription as originally written by T.E.'s physician, without any indication that the prescription had been partially dispensed on June 24, 2020.

16. On or about June 26, 2020, acting in reliance upon the information in the CVS computer system, Spears filled prescription number 88727 with a full 28-day supply of Oxycodone tablets. Spears placed the filled prescription in the pharmacy's waiting bin. Spears stated that he had not previously interacted with T.E. or been made aware of any issues with her prescription.

17. On or about July 24, 2020, T.E. picked up a full 28-day supply of Oxycodone tablets. According to T.E., a pharmacy employee handed her a bag without asking her to sign for the receipt of the contents or present photo identification. Respondent CVS was unable to produce a record of the July 24, 2020, transaction.

18. At no time between June 24, 2020, and July 24, 2020, did T.E.'s physician write her a second prescription for Oxycodone. According to Respondent Safavi, the CVS computer system did not generate a record of the transaction on July 24, 2020, because the system had already been programmed to reflect that prescription number 88727 was fully dispensed on June 24, 2020. As indicated above, Respondent Safavi was unable to modify or amend the applicable data entry.

19. As of October 16, 2020, Respondent CVS had not corrected pharmacy records to reflect that prescription number 88727 was only partially filled on June 24, 2020, and then filled a second time on July 24, 2020, with an excess number of Oxycodone 10 mg tablets.

APPLICABLE LAW

20. The Board may revoke or suspend the registration of any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4). Likewise, the Board may revoke or suspend the registration of any pharmacist who has violated any provision of Nevada law relating to prescription drugs. NRS 639.210(12). In lieu of revoking or suspending a pharmacist's registration, the Board may impose fines as a disciplinary measure. NRS 639.255; NAC 639.955.

21. A pharmacist's conduct is deemed unprofessional if the pharmacist fails to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling. NAC 639.945(1)(d). Additionally, a pharmacist's conduct is deemed unprofessional if the pharmacist performs his or her duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

22. Unless otherwise provided by law, a pharmacist must verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the

patient. Failure to provide appropriate counseling to the patient constitutes a violation of NRS 639.707(1). Pursuant to NRS 639.210(12), the Board may discipline a pharmacist who violates NRS 639.707(1).

23. Pursuant to NAC 639.910, a computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides a readily retrievable printed record of the information relating to a prescription or a patient which the pharmacy is required to maintain pursuant to state or federal law, including, without limitation, information relating to the original prescription or the refill or modification of that prescription.

24. Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy managers, and/or pharmacists are responsible for the acts and omissions of the pharmacy workers under their supervision and/or in their employ.

COUNT ONE
Failure to Counsel
(Respondents Safavi and CVS)

25. On or about June 24, 2020, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg. This was 42 fewer tablets than what had been prescribed by T.E.'s physician.

26. Respondent Safavi neglected to counsel T.E. before T.E. left the pharmacy with 14 tablets of Oxycodone.

27. Had Respondent Safavi properly counseled T.E., she would have alerted T.E. to the discrepancy between the number of tablets dispensed versus the number of tablets prescribed. This, in turn, would have alerted Respondent Safavi to correct the entry in the CVS computer system before it ostensibly became irreversible.

28. Respondent Safavi's conduct as alleged above violated NRS 639.707(1). Further, Respondent's conduct as alleged above was negligent. Accordingly, Respondent Safavi is subject to discipline pursuant to NRS 629.210(4), NRS 639.210(12), and NAC 639.945(1)(i).

29. As the owner/operator of the pharmacy at which Respondent Safavi was employed, Respondent CVS is responsible for Respondent Safavi's conduct as alleged above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

COUNT TWO
Failure to Follow Physician's Instructions
(Respondents Safavi and CVS)

30. On or about June 24, 2020, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg. This was 42 fewer tablets than what had been prescribed by T.E.'s physician.

31. Respondent Safavi did not obtain T.E.'s consent, nor the consent of T.E.'s physician, to deviate from the instructions on the prescription.

32. Having failed to obtain consent to deviate from the instructions on the prescription, Respondent Safavi failed to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling.

33. Having failed to obtain consent to deviate from the instructions on the prescription, Respondent Safavi performed her duties in a negligent manner.

34. Respondent Safavi's negligent conduct as alleged above was unprofessional. Accordingly, Respondent Safavi is subject to discipline pursuant to NRS 639.210(4) and NAC 639.945(1)(d) and (i).

35. As the owner/operator of the pharmacy at which Respondent Safavi was employed, Respondent CVS is liable for Respondent Safavi's' negligent conduct as described above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5) and NAC 639.945(2).

COUNT THREE
Failure to Follow Physician's Instructions
(Respondents Safavi and CVS)

36. On or about June 24, 2020, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg. This was 42 fewer tablets than what had been prescribed by T.E.'s physician.

37. Between June 24 and 26, 2020, Respondent Safavi attempted without success to edit pharmacy records to reflect that prescription number prescription number 88727 was partially and not fully dispensed on June 24, 2020. Although Respondent Safavi knew that her attempts to edit pharmacy records were unsuccessful, Respondent Safavi neglected to monitor the status of prescription number 88727.

38. As a result of Respondent Safavi's failure to monitor the status of prescription number 88727, another CVS pharmacist erroneously filled the prescription a second time by adding 56 Oxycodone tablets to the 14 tablets that had already been dispensed to T.E. This, in turn, caused Respondent CVS and/or its employees to dispense too many tablets to T.E, thus deviating from the instructions of the person writing, making, or ordering prescription number 88727 as to its filling or refilling.

39. Respondent Safavi's conduct as alleged above was negligent. Accordingly, she is subject to discipline for having engaged in unprofessional conduct. NRS 639.210(4); NAC 639.945(1)(d) and (i).

40. As the owner/operator of the pharmacy at which Respondent Safavi was employed, Respondent CVS is liable for Respondent Safavi's conduct as described above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5) and NAC 639.945(2).

COUNT FOUR
Failure to Maintain Accurate Records
(Respondent CVS)

41. On or about June 24, 2020, Respondent Safavi dispensed, or caused to be dispensed to patient T.E., a total of 14 tablets of Oxycodone 10 mg. This was 42 fewer tablets than what had been prescribed by T.E.'s physician.

42. On information and belief, Respondent CVS designed its computer system in such a way as to make it difficult if not impossible for Respondent Safavi to correct the history and status of prescription number 88727 as it appeared in pharmacy records.

43. As of October 16, 2020, Respondent CVS had not corrected pharmacy records to reflect that prescription number 88727 was only partially filled on June 24, 2020, and then filled a second time on July 24, 2020, with an excess number of Oxycodone 10 mg tablets.

44. Acting by and through its officers, employees, consultants, and/or independent contractors, Respondent CVS designed a computerized system that was incapable of providing a readily retrievable printed record of relevant information relating to prescription number 88727. Through this conduct, Respondent CVS violated NAC 639.910.

45. Based on the foregoing, Respondent CVS may be disciplined pursuant to NRS 639.210(12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Safavi and the pharmacy license of Respondent CVS.

DATED this 27th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NEGAR SAFAVI, RPH,** **Certificate Of Registration No. 18099,** **and,** **CVS Pharmacy # 6717** **License No. PH01932,** **Respondents.**	**Case Nos. 20-133-PH-S** **20-133-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, May 29, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South.
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 27th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NEGAR SAFAVI, RPH,** **Certificate Of Registration No. 18099,** **and,** **CVS Pharmacy # 6717** **License No. PH01932,** **Respondents.**	**Case Nos. 20-133-PH-S** **20-133-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

NEGAR SAFAVI, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of February 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Negar Safavi, PA
[redacted] Stuttgart St.
Las Vegas, NV 89147

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NEGAR SAFAVI, RPH,** **Certificate of Registration No. 18099,** **and,** **CVS PHARMACY #6717,** **Pharmacy License No. PH01932,** **Respondent.**	**Case No. 20-133-RPH-S** **20-133-PH-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its Senior General Counsel, Gregory L. Zunino, Respondent Negar Safavi ("Respondent Safavi"), and Respondent CVS Pharmacy #6717 ("Respondent CVS") hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Safavi and Respondent CVS (together "Respondents"), and this matter.

2. The Board's staff properly served each of Respondents with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondents agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.

4. Respondents acknowledge that they understand the terms of this Stipulation and Proposed Order ("Stipulation"), and they have executed it knowingly and voluntarily.

5. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondents under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative

procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that either of Respondents has failed to comply with the provisions of this Stipulation, Respondents hereby freely and voluntarily waive their rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Respondent Safavi admits that evidence exists, and that the Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One and Count Three of the Accusation. Although Respondent Safavi denies any direct, individual responsibility for the violation alleged in Count Three of the Accusation, Respondent Safavi acknowledges that pursuant to NAC 639.702, she is responsible for the violation because she was acting as managing pharmacist at the time of the violation and reasonably should have known of the acts and/or omissions of her subordinates. The parties further agree that Count Four of the Accusation does not apply to Respondent Safavi. Finally, the parties agree that Count Two of the Accusation arises from the same facts and circumstances as are alleged in Count One, such that Count Two is partially duplicative of Count One. Therefore, upon approval of this Stipulation by the Board, Count Two of the Accusation shall be dismissed with prejudice as to Respondent Safavi.

8. Respondent CVS admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One, Count Three, and Count Four of the Accusation. The parties agree that Count Two of the Accusation arises from the same facts and circumstances as are alleged in Count One, such that Count Two is partially duplicative of Count One. Therefore, upon approval of this Stipulation by the Board, Count Two of the Accusation shall be dismissed with prejudice as to Respondent CVS.

9. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent Safavi agree to the imposition of the following penalties:

A. Respondent Safavi shall pay an administrative fine of Five Hundred and No/100 Dollars ($500.00) as to each of the violations alleged in Count One and Count Three of the

Accusation, for a total administrative fine of One Thousand and 00/100 Dollars ($1,000.00). This sum shall be payable by *cashier's check, certified check, CVS company check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent Safavi shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

B. Respondent Safavi shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check, CVS company check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent Safavi shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

10. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent CVS agree to the imposition of the following penalties:

A. Respondent CVS shall pay an administrative fine of Five Hundred and No/100 Dollars ($500.00) as to each of the violations alleged in Count One, Count Three, and Count Four of the Accusation, for a total administrative fine of One Thousand Fine Hundred and 00/100 Dollars ($1,500.00). This sum shall be payable by *cashier's check, certified check, business check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent CVS shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

B. Respondent CVS shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check, business check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent CVS shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

11. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 20-133-RPH-S as to Respondent Safavi, and a full and final resolution of the Accusation in Case No. 20-133-PH-S as to Respondent CVS. However, failure by either Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing the noncompliant Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by that Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

12. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents fails to appear for the meeting.

13. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

14. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

15. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED: 8/20/24

Signed this ____ day of _____ 2024.

NEGAR SAFAVI

Signed this ____ day of _____2024.

GREGORY L. ZUNINO
Senior General Counsel

Signed this ___ day of _____2024

CVS PHARMACY # 6717

By: Pharmacist
Name: Negar Safavi
Title: Pharmacy Manager

DECISION AND ORDER

As to Respondent Negar Safavi and Respondent CVS Pharmacy #6717, in Case No. 20-133-RPH-S and Case No. 20-133-PH-S, respectively, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 4th day of September 2024.

Helen Park, President
Nevada State Board of Pharmacy

AGREED:

Signed this ____ day of _____ 2024.

NEGAR SAFAVI

Signed this 21st day of Aug 2024.

GREGORY L. ZUNINO
Senior General Counsel

Signed this 16th day of Aug 16, 2024 **2024**

CVS PHARMACY # 6717

By: _____
Name: Leigh Parenteau
Title: Sr. Manager, Pharmacy Regulatory Affairs

DECISION AND ORDER

As to Respondent Negar Safavi and Respondent CVS Pharmacy #6717, in Case No. 20-133-RPH-S and Case No. 20-133-PH-S, respectively, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 4th day of September 2024.

Helen Park, President
Nevada State Board of Pharmacy

5X

FILED
MAR 2 2 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JONES FEED AND TACK,** **Permit No. VDS00026,** **Respondent.**	**CASE NO. 21-064-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Jones Feed and Tack (Respondent), because Respondent currently holds a permit issued by the Board pursuant to NRS 639.2345 and NAC 639.650, authorizing Respondent to sell veterinary drugs.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violation involves unpermitted sales of veterinary drugs.

FACTUAL ALLEGATIONS

3. Respondent is currently permitted by the Board to sell veterinary drugs from its business location at 6515 W. Lone Mountain Road in Las Vegas, Nevada. Respondent's sister location is separately permitted by the Board to sell veterinary drugs at 8174 S. Las Vegas Boulevard #111A in Las Vegas, Nevada.

4. In November 2018, Respondent neglected to renew the permit for its business location at 6515 W. Lone Mountain Road.

5. In May 2021, Board staff learned that Respondent was selling veterinary drugs from its location at 6515 W. Lone Mountain Road. Board Investigator Kenneth Scheuber contacted David

Singh, manager, who acknowledged that he had forgotten to renew the permit for the location at 6515 W. Lone Mountain Road. That permit came due for renewal on November 1, 2018.

6. Since 2016, Mr. Singh has continuously maintained a permit for Respondent's sister location at 8174 S. Las Vegas Boulevard #111A in Las Vegas, Nevada.

7. Mr. Singh acknowledged that between November 1, 2018, and May 12, 2021, Respondent sold veterinary drugs from Respondent's unpermitted location at 6515 W. Lone Mountain Road.

8. In November 2020, Mr. Singh attempted through the Board's on-line portal to renew Respondent's permit for the location at 6515 W. Lone Mountain Road. The system did not process the renewal request because the permit had expired more than two years earlier. By email, Board staff advised Mr. Singh that he would have to apply for a new permit.

9. On May 17, 2021, Mr. Singh applied for a new permit for the location at 6515 W. Lone Mountain Road.

10. In 2022, the Board approved Respondent's application and issued a new permit for the location at 6515 W. Lone Mountain Road.

APPLICABLE LAW

11. In Nevada, it is unlawful for any person to sell drugs without the applicable license or permit. NRS 639.100(1). "Drug" is defined to include drugs or medicines intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals. NRS 639.007(2).

12. Any person who engages in the sale of veterinary prescription or nonprescription drugs must obtain a permit from the Board. NRS 639.2345(1). "The fee for a biennial permit, valid for a 2-year period commencing November 1 of each even-numbered year, is $300." NAC 639.650(1).

13. In addition to any criminal or civil penalties that may apply, the Board may revoke or suspend the permit of any person who has been guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4). Likewise, the Board may revoke or suspend the permit of any person who has violated any Nevada law or regulation relating to drugs. NRS 639.210(12).

14. A person's conduct is deemed unprofessional and/or contrary to the public interest if the person performs any act, task or operation for which licensure, certification or registration is required without the required license, certificate, or registration. NAC 639.945(1)(h).

15. In addition to or in lieu of revoking or suspending a person's permit due to an act or omission described above, the Board may impose an administrative fine upon the person. The fine may not exceed $10,000 for each offense. NRS 639.255(1)(f) and (3).

COUNT ONE

Selling Veterinary Drugs Without a Permit

16. Between November 1, 2018, and May 12, 2021, as alleged above, Respondent sold veterinary drugs from Respondent's unpermitted location at 6515 W. Lone Mountain Road. This constitutes a violation of Nevada law for which the Board may impose administrative discipline. NRS 639.210(1); NRS 639.210(12). It also constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4); NAC 639.945(1)(k).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the current permit of this respondent.

DATED this 22nd day of March 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JONES FEED AND TACK,** **Permit No. VDS00026,** **Respondent.**	**Case No. 21-064-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JONES FEED AND TACK,** **Permit No. VDS00026,** **Respondent.**	**Case No. 21-064-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

AUTHORIZED REPRESENTATIVE FOR JONES FEED AND TACK

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of March 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

JONES FEED AND TACK
6515 W Lone Mountain Rd.
Las Vegas, NV 89130

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
MAR 2 2 2024
NEVADA STATE BOARD OF PHARMACY

Jones Feed and Tack
6515 W Lone Mountain Rd.
Las Vegas, NV 89130
21-064-S. NIAA

MAILED
3/29/24

9171 9690 0935 0313 8196 17

Certified - $9.68

Regular - $1.87

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

August 5, 2024

Jones Feed and Tack
6515 W Lone Mountain Rd
Las Vegas, NV 89130

Re: Jones Feed and Tack and Case No. 21-064-5

Dear Jones Feed and Tack,

The hearing for case number 21-064-5 has been scheduled for **Wednesday, September 4, 2024** at **9:00AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Board Coordination
Nevada State Board of Pharmacy

9171 9690 0935 0314 1914 84

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LAS VEGAS, NV 89130
August 9, 2024, 12:45 pm

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JONES FEED AND TACK,** **Certificate of Registration No. VDS00026,** **Respondent.**	**Case Nos. 21-064-S** **MEMORANDUM OF COSTS AND FEES**

Pursuant to NRS 622.400, the undersigned hereby submits the following itemized bill of costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

Investigation Time (Investigator Kenneth Scheuber)

Date(s)	Description	Hours	Rate	Amount
2021	See attached	12	$50.00	$600.00
Subtotal (Investigation):				$600.00

Attorney Time (Gregory Zunino)

Date(s)	Description	Hours	Rate	Amount
3/21/2024	Review File, Draft Accusation	1.5	$60.00	$90.00
3/22/2024	Review File, Finalize Accusation	1.25	$60.00	$75.00
8/16/2024	Review File, Call to Jones Feed and Tack, Email to Jones Feed and Tack	.25	$60.00	$15.00
8/20/2024	Review File, Email to Jones Feed and Tack	.25	$60.00	$15.00
8/20/2024	Assemble Exhibits for Hearing	2.0	$60.00	$120.00
9/4/2024	Hearing (Estimated)	.75	$60.00	$75.00

Subtotal (Attorney Time)		$390.00

Administrative Costs

Date(s)	Description	Amount
3/29/2024	Postage	$11.56
8/7/2024	Postage	$11.56
Subtotal (Administrative Costs)		$23.12
Total Costs and Fees:		**$1,013.12**

I, Gregory L. Zunino, affirm, to the best of my knowledge and belief, that the foregoing is a true and correct statement of costs and reasonable attorney's fees incurred by the Board in the above-entitled action.

DATED this 20th day of August 2024.

/s/ Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy

CASE NUMBER 21-064-S

INVESTIGATION HOURS

KENNETH SCHEUBER

DATE	ACTIVITY	TOTAL HRS
5-11-2021	CASE RECEIVED AND REVIEWED. MADE A PAPER FILE.	2.0
	ELECTRONIC FILE AND REPORT CREATED. PULLED CONTACT	
	INFORMATION INCLUDING LICENSE INFO FROM INFUMON.	
5-12-2021	VISITED THE SITE. I VALIDATED THE POSTED LICENSE	1.5
	EXPIRED ON 10/31/2018.	
5-13-2021	INTERVIEWED THE OWNER DAVID SINGH. REGARDING	.5
	THE NON-RENEWAL. DAVID SAID HE SENT IN THE APPLICATION	
	AND FEES	
5-14-2021	D. SINGH PROVIDED A STATEMENT REGARDING HIS	
	ERROR IN THE FAILURE TO RENEW HIS LICENSE AT	.5
	THE LONE MOUNTAIN LOCATION	
5-28-2021	TYPED THE CASE COMPLETE. INCLUDING COVER PAGES	4.0
	FOR ATTACHMENTS	
6-10-2021	LAS VEGAS REVIEW COMMITTEE APPROVED CASE TO BE	
	FORWARDED TO DAVE + YENIT FOR ACTION IF NECESSARY.	.25
7-30-2021	DAVE AND YENIT REQUESTED I CONTACT THE OWNER	
	FOR SALES INFORMATION DURING THE UNLICENSED PERIOD.	.25
8-6-2021	CONTACTED DAVE SINGH FOR SALES INFO.	.50
8-9-2021	DAVID PROVIDED THE SALES INFORMATION	.25
8-12-2021	YENIT LONG CONFIRMED SALES INFORMATION IS ACCEPTABLE	.50
8-13-2021	UPDATED THE CASE RE-REVIEW AT NEXT REVIEW	1.50
	COMMITTE MEETING	
	ENTER CASE BACK INTO INFUMON	.25
8-24-2021	COMMITTEE REVIEW	
	TOTAL TIME	12.0

Investigator Signature Kenneth Scheuber Date 8-24-21

Timesheet for Darlene Nases –

JONES FEED AND TACK - CASE NO. 21-064-S

DATE	TIME
2/01/22	0.25

Sent Cease and Desist via certified mail to Jones Feed and Tack & the Owner (David Singh)

TOTAL 0.25 hours x $39.84 hour = $9.96
Total Mailing Cost: $14.66

<u>OVERALL TOTAL</u>: $24.62

Timesheet for Erin Miller –

JONES FEED AND TACK - CASE NO. 21-064-S

DATE	TIME
Mailed Accusation	0.5
Mailed 21-day letter	0.5

TOTAL 1.0 hours x $30/hour = $30
Total Mailing Cost: $21.88

<u>OVERALL TOTAL</u>: $51.88

5Y

FILED
JUN 18 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ANGELINA BUCU, APRN,** **Certificate of Registration No. CS29531,** **Respondent.**	**Case No. 21-072-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Angelina Bucu, APRN (Respondent), because Respondent holds a certificate of registration issued by the Board pursuant to NRS 453.226. This certificate of registration authorizes Respondent to prescribe controlled substances in Nevada.

2. The Board has jurisdiction over the subject matter of this accusation because it concerns Respondent's alleged noncompliance with a statutory obligation to monitor her own prescribing activity and that of other practitioners relative to Respondent's Nevada patients. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent is licensed by the Nevada State Board of Nursing to practice advanced nursing. At the time of the violations alleged herein, Respondent was a "practitioner" as that term is defined at NRS 453.126(2) and 639.0125(3).

4. Between November 1, 2020, and October 31, 2022, Respondent held a certificate of registration issued by the Board pursuant to NRS 453.226. This certificate of registration authorized Respondent to prescribe controlled substances. Respondent had previously held a certificate of registration for the period from November 13, 2019, to October 31, 2020. Respondent currently holds

a certificate of registration that was issued on November 1, 2022, and is due to expire on October 31, 2024.

5. On November 13, 2019, Respondent established an account with Nevada's Prescription Monitoring Program (PMP). The account provided Respondent with individual access to the PMP database, a confidential source of information concerning all prescriptions written in Nevada for controlled substances.

6. According to the Board's records, Respondent first accessed the PMP database on February 1, 2022. Prior to that date, Respondent had never accessed the PMP database to review her own prescribing activity or to evaluate the prescription histories of the patients for whom she prescribed controlled substances.

7. Between December 16, 2019, and July 31, 2021, Respondent wrote 1,349 prescriptions for controlled substances, including refills. Respondent wrote these prescriptions for 480 different Nevada-based patients.

8. Between November 18, 2020, and January 31, 2021, Respondent worked at the Extensive Pain, Primary and Urgent Care Center of Nevada (Extensive Pain), located at 6465 W. Sahara Avenue, Suite 103, in Las Vegas, Nevada. For a short period of time, Respondent worked at Extensive Pain with another nurse practitioner by the name of Twyla Russell (RN Russell). RN Russell passed away on November 25, 2020.

9. Between November 25, 2020, and January 31, 2020, Respondent assumed responsibility for some or all of RN Russell's former patients. Respondent wrote controlled substance prescriptions for these patients on December 4, 2020, December 17, 2020, January 6, 2021, and January 14, 2021.

10. Respondent did not individually query the PMP database concerning RN Russell's former patients. Instead, Respondent knowingly permitted, caused, or directed a non-practitioner, Arvin Videna, to access the PMP database on Respondent's behalf. Videna accessed the PMP database using the account and credentials that had been assigned to RN Russell.

11. Arvin Videna was never authorized, per NAC 453.070, to access the PMP database as a "delegate" of either Respondent or RN Russell.

APPLICABLE LAW

12. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. NRS 453.056.

13. Every practitioner who intends to prescribe controlled substances in Nevada must first apply for and obtain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). The practitioner must renew the certificate of registration on a biennial basis. *Id.* A practitioner who fails to register or renew may be subject to criminal and/or civil penalties for prescribing controlled substances without a certificate of registration. NRS 453.232; NRS 453.553; NRS 453.5531.

14. When a practitioner first obtains a certificate of registration to prescribe controlled substances, the practitioner must enroll in the PMP and complete a course of instruction concerning the use of the PMP database. NRS 453.164(5) & (6); NAC 453.065.

15. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

16. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

17. A practitioner may designate not more than two members of his or her staff to act as delegates for the purpose of accessing the PMP database. NAC 453.070(1). Before accessing the PMP database, a delegate must complete a course of instruction concerning the use of the PMP. NAC 453.070(2).

18. With a few exceptions, the patient and prescription information in the PMP database is confidential. NRS .453.164(8). A practitioner has a duty to maintain the confidentiality of this information.

19. The Board may revoke or suspend the registration of any practitioner who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

20. The Board may revoke or suspend the existing registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

21. A practitioner's conduct is deemed unprofessional and/or contrary to the public interest if the practitioner performs his or her duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i) and (k).

22. A practitioner's conduct is deemed unprofessional and/or contrary to the public interest if the practitioner fails to provide any document, data, or information that is required to be made and maintained pursuant to the statutes and regulations governing the PMP. NAC 639.945(1)(m).

23. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon the practitioner. The fine may not exceed $10,000 for each offense. NRS 639.255(1)(f) and (3).

COUNT ONE

Noncompliance with Prescription Monitoring Program

24. As alleged above, between December 16, 2019, and July 31, 2021, Respondent failed to query the PMP database regarding her patients' histories of using controlled substances. The PMP database compiles a controlled substance utilization report for any practitioner who makes such a query. The controlled substance utilization report provides the practitioner with evidence as to whether a patient is doctor-shopping and/or abusing controlled substances.

25. As alleged above, between December 16, 2019, and July 31, 2021, Respondent failed to query the PMP database regarding her own prescriber activity. The PMP database compiles a report

of prescribing activity for any practitioner who makes such a query. This allows the practitioner to evaluate whether anyone has fraudulently used the practitioner's credentials to prescribe controlled substances.

26. As alleged above, between December 16, 2019, and July 31, 2021, Respondent wrote 1,349 prescriptions for controlled substances, including refills, for 480 different Nevada-based patients.

27. By failing to query the PMP database to review her patients' utilization report prior to issuing a prescription for a controlled substance, and by failing to review her own prescriber activity on a semi-annual basis, Respondent violated NRS 453.164(7) and NRS 639.23507. These are violations of state law and acts that render Respondent's Nevada controlled substance registration inconsistent with the public interest. Therefore, the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 639.255(3), NRS 453.236(1)(d) and (e), and NRS 453.241(1).

COUNT TWO

Unprofessional Conduct by a Practitioner

28. As alleged above, between November 25, 2020, and January 31, 2020, Respondent assumed responsibility for some or all of RN Russell's former patients. Respondent wrote controlled substance prescriptions for these patients on December 4, 2020, December 17, 2020, January 6, 2021, and January 14, 2021.

29. Respondent did not individually query the PMP database concerning RN Russell's former patients. Instead, Respondent knowingly permitted, caused, or directed a non-practitioner, Arvin Videna, to access the PMP database on Respondent's behalf. Videna accessed the PMP database by using the account and credentials that were assigned to RN Russell.

30. Because Arvin Videna had not been designated as a delegate with permission to access the PMP database, Respondent breached her duty to protect the confidentiality of the information in the PMP database. Therefore, Respondent performed her duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner.

31. As alleged above, Respondent's acts and/or omissions constitute unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4); NAC 639.945(1)(i).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Angelina Bucu.

DATED this 18th day of JUNE 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ANGELINA BUCU, APRN** **Certificate Of Registration No. CS29531,** **Respondent.**	**Case No. 21-072-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 18th day of JUNE 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of June 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Angelina Bucu, APRN
Driven Care Telemedicine
18800 Delaware St., Suite 800
Huntington Beach, CA 92648

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ANGELINA BUCU, APRN,** **Certificate of Registration Nos. CS29531,** **Respondent.**	**Case No. 21-072-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Gregory L. Zunino, Esq., and Respondent Angelina Bucu, APRN ("Respondent"), by and through counsel, Kevin Murphy, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy (the "Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that she understands the terms of this Stipulation and Order ("Stipulation") and has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives her right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One and Count Two of the Accusation. In this regard, Respondent admits that between December 16, 2019, July 31, 2023, she did not access the prescription monitoring program database for the purpose of reviewing her prescribing activity, as required by NRS 453.164(7), and she did not review patient utilization reports in instances where such review was required pursuant to NRS 639.23507. Respondent further admits that in 2020 and 2021, she permitted an authorized person or persons to access the PMP database on her behalf.

7. Respondent represents that she has read and is familiar with the provisions of NRS 453.164(7) and NRS 639.23507 concerning the use of, and access to, the prescription monitoring program database, and has educated herself on the proper use of said database.

8. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the parties agree to the imposition of the following penalties as to the violations alleged in Count One and Count Two of the Accusation, to wit:

A. Respondent accepts this Stipulation as a public reprimand issued pursuant to NRS 639.255(1)(e).

B. Respondent shall pay an administrative fine of **Two Thousand Five Hundred and 00/100 Dollars ($2,500.00)**, payable by *cashier's check, certified check,* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before December 31, 2024.

C. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before December 31, 2024.

9. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 21-072-CS-S. However, Respondent understands and acknowledges that her failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

10. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

11. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60. If approved, this Stipulation shall become effective as of the date upon which the Board enters its written order below.

12. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Stipulation.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of _____2024.

ANGELINA BUCU, APRN
Certificate of Registration No. CS29531

Signed this 16th day of Aug, 2024.

GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

APPROVED AS TO FORM:

KEVIN MURPHY, ESQ.
Nevada Bar No. 10938

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of _____2024.

ANGELINA BUCU, APRN
Certificate of Registration No. CS29531

Signed this ____ day of _____2024.

GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

APPROVED AS TO FORM:

KEVIN MURPHY, ESQ.
Nevada Bar No. 10938

ORDER

As to Respondent Angelina Bucu, APRN, in Case No. 21-072-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of September 2024.

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9842,** **Pharmacy License No. PH01422,** **Respondent.**	**Case No. 22-169-PH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent CVS Pharmacy #9842 ("CVS #9842"), because at the time of the events alleged herein, Respondent CVS #9842 held Pharmacy License No. PH01422, issued by the Board, pursuant to NRS 639.230, on October 1, 1999, which authorized Respondent CVS #9482 to operate a pharmacy within the State of Nevada.

2. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent CVS #9842 operated a pharmacy in the State of Nevada.

FACTUAL ALLEGATIONS

3. Respondent CVS #9842 operated a pharmacy at 1980 N. Carson St., Carson City, NV 89701 at the time of the events alleged herein.

4. On or about June 6, 2022, an electronic prescription for thirty tablets of dextroamphetamine-dextroamphetamine ER 30 mg ("Adderall"), a schedule II-controlled substance, was transmitted to CVS #9842 and identified as RX #1100905 by CVS #9842's computer system.

5. CVS #9842's computer system reflects that RX #1100905 was deleted by an unidentified employee on June 14, 2022.

6. On or about June 15, 2022, the Board received a complaint stating that when the patient's family member attempted to pick up RX #1100905, CVS #9842 had not filled RX #1100905 and had deleted the electronic prescription record because the prescription was out of stock.

7. On June 22, 2022, the patient's family member requested CVS #9842 contact the prescribing practitioner to request a new Adderall prescription be electronically transmitted to the CVS #9842.

8. On June 30, 2022, a new prescription for Adderall was electronically transmitted to CVS #9842. The new Adderall prescription was identified as RX #1105228 by CVS #9842's computer system and filled the same day.

9. CVS was unable to produce a copy of RX #1100905 in response to a request from the Board's investigator.

10. CVS #9842 failed to maintain a computerized system for its prescription records that maintained a readily accessible copy of RX #1100905 for a period of at least two years and prevented its deletion by an unidentified user.

APPLICABLE LAW

11. A pharmacist who receives a prescription transmitted electronically shall keep a paper copy of the prescription for at least 2 years after the pharmacist receives the prescription. The copy of the prescription that is kept must be readily accessible to the personnel of the pharmacy who are authorized to access records of prescriptions kept by the pharmacy; and members, employees, agents, and designees of the Board. NAC 639.7105.

12. Any computerized systems used by a pharmacy for recording information concerning prescriptions must be designed in a manner that it provides: a readily retrievable printed record of information relating to a prescription or a patient which the pharmacy is required

to maintain pursuant to state or federal law, including, without limitation, information relating to the original prescription or the refill or modification of that prescription; the original prescription number; the prescribing practitioner's name, address and the registration number issued to him or her by the Drug Enforcement Administration if the prescribing practitioner is registered with that agency; the full name and address of the patient; the date on which the original prescription was filled, if it is different from the date prescribed; the name, strength, form, dosage, quantity and directions for use of the drug prescribed; the name or common abbreviation of the manufacturer, packer or distributor or the National Drug Code number of the drug dispensed to the patient; the total number of refills authorized by the prescriber; the date and quantity of each refill of a drug dispensed to a patient; the total number of refills of a drug dispensed to a patient; the quantity dispensed, if that is different from the quantity prescribed; at the time a prescription is filled or refilled, an automatic notice of the information the pharmacist, intern pharmacist or dispensing practitioner considered pursuant to subsection 4 of NAC 639.707; a procedure that may be conducted at least once each day to ensure that the information which is recorded in the system is not lost or destroyed. NAC 639.910(1).

13. A computerized system used by a pharmacy must have adequate safeguards to identify whether information in the system concerning a prescription was modified or manipulated; the manner in which the information was modified or manipulated; the date on which the information was modified or manipulated; and the person who modified or manipulated the information. The computerized system must also prevent the removal of a record or a prescription after the system has assigned a number to the prescription. NAC 639.930(1-5). NAC 639.935(4)(b).The computerized system used by a pharmacy must be able to produce a printed record of the above-identified information upon request by a member, inspector or investigator of the Board. NAC 639.935(4)(b).

14. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(4) upon a finding that the holder performed his or her duties as the holder

of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

15. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(12) upon the finding that the holder, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

16. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

17. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

18. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

19. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

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COUNT ONE

Failure to Keep Copy of Electronic Prescription for Two Years
(Respondent CVS #9842)

20. By failing to produce a copy of RX #1100905, an electronic prescription, upon a request from the Board's investigator, Respondent CVS #9842 violated NAC 639.7105, because it failed to keep a readily accessible paper copy of the prescription for a period of at least two years. As the owner of pharmacy, and/or pursuant to NRS 639.230(5), and/or NAC 639.945(2), and/or NAC 639.702, Respondent CVS #9842 is responsible the violations and/or for the acts its employees and is therefore subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.255(3).

COUNT TWO

Failure to Maintain a Computerized System which Prevents Deletion of Prescription Records
(Respondent CVS #9842)

21. By maintaining a computerized system which allowed for deletion of RX #1100905 on or about June 14, 2022, without identification of the employee who initiated the deletion, Respondent CVS #9842 violated NAC 639.930(3-5) and NAC 639.935(3)(f), (g)(3-4), and (4)(b). As the owner of pharmacy, and/or pursuant to NRS 639.230(5), and/or NAC 639.945(2), and/or NAC 639.702, Respondent CVS #9842 is responsible the violations and/or for the acts its employees and is therefore subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.255(3).

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COUNT THREE

Unprofessional Conduct

(Respondent CVS #9842)

22. By failing to produce a copy of RX #1100905 upon the request and by maintaining a computerized system which allowed for deletion of RX #1100905, Respondent CVS #9842, engaged in unprofessional conduct in violation as defined in NAC 639.945(1)(i). As the owner of pharmacy, and/or pursuant to NRS 639.230(5), and/or NAC 639.945(2), and/or NAC 639.702, Respondent CVS #9842 is responsible the violations and/or for the acts its employees and is therefore subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.255(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 18th day of March 2024.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9842,** **Pharmacy License No. PH01422,** **Respondent.**	**Case No. 22-169-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 18th day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9842,** **Pharmacy License No. PH01422,** **Respondent.**	**Case No. 22-169-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY #9842

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 18th day of March 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

CVS Pharmacy #9842
1980 N Carson St
Carson City, NV 89701

Brian J. Convery, Esq.
200 Campus Dr, Suite 310
Florham Park, NJ 07932

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT I
BOARD COORDINATOR

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9842,** **License No. PH01422,** **Respondent.**	**CASE NO. 22-169-PH-N** **STIPULATION AND ORDER**

Gregory Zunino, Senior General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent CVS Pharmacy #9842, License No. PH01422, **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.

2. On or about March 18, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as both parties pursued settlement negotiations.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to them pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives their rights to

a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violation alleged in Count One of the Accusation. Regarding Count Two and Count Three of the Accusation, Respondent maintains that the prescribing practitioner, not an unidentified CVS employee, deleted electronic prescription number 1100905 before Respondent's computer system could preserve a permanent record of the prescription. Respondent disputes that its computer system is inadequate as a matter of law, but Respondent acknowledges that Respondent failed to produce a hard copy of the prescription at the request of the Board's investigator. Therefore, in the interest of compromise, Count Two and Count Three of the Accusation shall be dismissed upon approval of this Stipulation by the Board.

8. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agrees to the imposition of the following penalties:

A. Respondent shall pay **Five Hundred Dollars ($500.00)** for the violation alleged in Count One of the Accusation, payable by *cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, not later than October 15, 2024;

B. Respondent shall pay **Five Hundred Dollars (500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check or certified check or money order* made payable to **"Nevada State Board of Pharmacy,"** to be received by the Board's Reno office

located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, not later than October 15, 2024.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an Order to Show Cause pursuant to NAC 639.965 directing that Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. The Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 639;

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting;

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board it shall be a public record pursuant to NRS 622.330;

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and agreement herein may not be used or referred to in a full hearing on the merits of this matter;

13. This matter will be reported to the National Practitioner Data Bank as required by 45 C.F.R. §§ 60.3; 60.5; and 60.9;

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has

freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of Aug 13, 2024 **2024**

CVS PHARMACY #9842

BY: _____

Signed this 15th **day of** Aug **2024**

_____

GREGORY ZUNINO
Senior General Counsel
Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent CVS Pharmacy #9842, License No. PH01422, in Case No. 22-169-PH-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 4th day of September, 2024.

_____

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CANDICE DENHAM, DVM, Certificate of Registration Nos. CS35349, and DV00822,** **Respondent.**	**Case No. 23-257-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Candice Denham, D.V.M. (Respondent), because the violations alleged herein, weigh on Respondent's character to hold certificates of registration issued by the Board pursuant to NRS 453.226 to prescribe controlled substances and NRS 639.100 to dispense drugs. Since April 19, 2023, Respondent has held certificate of registration number CS35349 to prescribe controlled substances issued by the Board pursuant to NRS 453.226 and certificate of registration number DV00822 to dispense drugs pursuant to NRS 639.100.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent has been licensed by the Board to prescribe controlled substances (CS35349) since April 19, 2023. NRS 453.226. Such a license authorizes the holder to write prescriptions for controlled substances. NRS 453.226.

4. Respondent has been licensed by the Board to dispense drugs (DV00822) since April 19, 2023. NRS 639.100. Such a license authorizes the holder to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner. NRS 639.0065.

5. Respondent submitted a controlled substance application and an application for veterinary authority to dispense drugs, both signed on April 12, 2023, that stated she had never been the subject of a board citation or administrative action whether completed or pending in any state.

6. It later came to the Board's attention that Respondent had voluntarily surrendered her DEA Certificate of Registration No. FS5781263 in the State of Hawaii on February 24, 2023.

7. Respondent had admitted at the time to the DEA that she had been using stimulants.

8. On November 2, 2023, Respondent's controlled substance license was suspended pursuant to NRS 639.2107.

APPLICABLE LAW

9. If a regulatory body revokes the license of a person in a contested case pursuant to this chapter, the regulatory body shall prescribe a period during which the person may not apply for reinstatement of the license. The period must not be less than 1 year and not more than 10 years. NRS 622A.410(1).

10. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

11. Unprofessional conduct includes, "performing or in any way being a party to any fraudulent or deceitful practice or transaction. NAC 639.945(1)(h).

12. The Board may suspend or revoke any registration if the holder or applicant has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent. NRS 639.2010(10).

13. The Board may revoke or suspend a registration if a respondent has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this

chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

14. A person may not secure or attempt to secure any certificate, license or permit issued by the Board for themselves by making, or causing to be made, any false representation. NRS 639.281(1).

15. In lieu of a suspension or revocation, or in concert with it, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE
Unprofessional Conduct by a DVM

16. Respondent applied for a certificate of registration with the Board to prescribe controlled substances pursuant to NRS 453.226. On the Board's controlled substance application, question three of section five asks whether the applicant has been the subject of a board citation or an administrative action whether completed or pending in any state. Respondent also applied for veterinarian authority to dispense drugs pursuant to NRS 639.100. On the Board's application for veterinarian authority to dispense drugs, question three of section four asks the same question, whether the applicant has been the subject of a board citation or administrative action whether completed or pending in any state. Respondent answered "no" to this question on both applications. Respondent answered "no" even though she had voluntarily surrendered her Hawaii DEA Registration Number FS 5781263 on February 24, 2023.

17. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed or was a party to a fraudulent or deceitful practice or transaction. NAC 639.945(1)(h).

18. Respondent performed or was a party to a fraudulent or deceitful practice or transaction because Respondent failed to disclose that she had voluntarily surrendered her Hawaii DEA Certificate of Registration. *See* NAC 639.945(1)(h). Respondent also performed or was a party to a fraudulent or deceitful practice or transaction because Respondent failed to truthfully answer question three of section five on the Board's controlled substance registration and question three of section four of the Board's application for veterinarian authority to dispense drugs. *See* NAC 639.945(1)(h).

19. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NRS 639.281; NAC 639.945; and NAC 639.955.

COUNT TWO

Obtaining a Certificate of Registration by the Filing of a False Application

20. Respondent filed a false application with the Board when her controlled substance application and her application for veterinary authority to dispense drugs neglected to disclose her voluntary surrender of her DEA Certificate of Registration.

21. The Board may suspend or revoke any registration if the holder or applicant has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent. NRS 639.2010(10). Additionally, a person may not secure or attempt to secure any certificate, license or permit issued by the Board for themselves by making, or causing to be made, any false representation. NRS 639.281(1).

22. Respondent's application was obtained by the filing of a false application because she neglected to disclose that she voluntarily surrendered her DEA certificate of registration less than two months before she sent in her applications to the Board. *See* NRS 639.210(10); NRS 639.281(1); and NRS 639.281(2).

23. Having obtained a certificate of registration from the Board by the filing of a false application, Respondent is subject to discipline by the Board. NRS 639.210(10); NRS 639.255; NRS 639.281; and NAC 639.955.

COUNT THREE
Violations of NRS Chapter 639

24. By filing an application with the Board that neglected to include Respondent's voluntary surrender of her DEA Certificate of Registration, she violated NRS 639.210(4), NRS 639.210(10), and NRS 639.281.

25. The Board may revoke or suspend a registration if a respondent has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

26. Respondent violated or attempted to violate provisions of NRS Chapter 639 when she failed to disclose to the Board that she voluntarily surrendered her DEA Certificate of Registration on February 24, 2023. *See* NRS 639.210(12).

27. These actions violated NRS 639.210(4) because she engaged in unprofessional conduct by being a party to a fraudulent or deceitful practice or transaction. *See* NRS 639.210(4); NRS 639.210(12); and NAC 639.945(1)(h). Respondent violated NRS 639.210(10) and NRS 639.281 because she obtained a certificate of registration from the Board by the filing of a false application. NRS 639.210(10); NRS 639.210(12); and NRS 639.281.

28. Having committed violations of NRS Chapter 639, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.210(10); NRS 639.210(12); NRS 639.255; NRS 639.281; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 14th day of NOVEMBER 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CANDICE DENHAM, DVM,** **Certificate of Registration Nos. CS35349, and DV00822,** **Respondent.**	**CASE NO. 23-257-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of NOVEMBER 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CANDICE DENHAM, DVM, Certificate of Registration Nos. CS35349, and DV00822,** **Respondent.**	**CASE NO. 23-257-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

CANDICE DENHAM, DVM

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of November 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Candice Denham, DVM
[redacted] West Elkhorn Rd
North Las Vegas, NV 89084

Candice Denham, DVM
[redacted] Emerald Cove Ct.
Las Vegas, NV 89117

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CANDICE DENHAM, DVM,** **Certificate of Registration Nos. CS35349 and DV00822,** **Respondent.**	**Case No. 23-257-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Gregory L. Zunino, Esq., and Respondent Candice Denham, DVM, ("Respondent"), hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy (the "Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.

4. Respondent acknowledges that she understands the terms of this Stipulation and Order ("Stipulation") and has executed it knowingly and voluntarily.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this

Stipulation, Respondent hereby freely and voluntarily waives her right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation. In this regard, Respondent admits that she applied to the Board for certificates of registration to prescribe and dispense controlled substances in Nevada and failed to disclose that she had previously surrendered her certificate of registration to prescribe controlled substances as issued by the federal Drug Enforcement Administration (DEA). Further, Respondent admits that she responded "no" to questions on the Board's applications asking whether she had "been the subject of a board citation or administrative action whether completed or pending in any state."

8. Respondent has been advised and understands that she cannot hold certificates of registration to prescribe and dispense controlled substances in Nevada unless she simultaneously holds a current DEA registration number.

9. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agrees to the imposition of the following penalties:

A. Respondent's Certificate of Registration Nos. CS35349 and DV00822 shall be **REVOKED**, and Respondent shall not be eligible to petition for the reinstatement of her privileges to prescribe and dispense controlled substances in Nevada for a period of one (1) year from the effective date of this Stipulation, or until Respondent secures a DEA registration number in Nevada, whichever is later.

B. Respondent shall pay an administrative fine of **One Thousand and 00/100 Dollars ($1,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

C. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

10. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 23-257-CS-S. However, Respondent understands and acknowledges that her failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

11. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

12. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60. If approved, this Stipulation shall become effective as of the date upon which the Board enters its written order below.

13. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Stipulation.

AGREED:

Signed this 19th **day of** August **2024.**

CANDICE DENHAM, DVM
Certificate of Registration Nos. CS35349 and DV00822

Signed this 20th **day of** Aug **2024.**

GREGORY L. ZUNINO
Senior General Counsel

ORDER

As to Respondent Candice Denham, DVM, in Case No. 23-257-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of September 2024.

Helen Park, President
Nevada State Board of Pharmacy

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FILED
JUN 17 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TAMMARA BEEGHLY, PA,** **Certificate of Registration No. CS12793,** **Respondent.**	**Case No. 23-274-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Tammara Beeghly, P.A. (Respondent), because the violations alleged herein, weigh on Respondent's character to hold a certificate of registration issued by the Board pursuant to NRS 453.226, authorizing Respondent to write prescriptions for controlled substances.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations require the Board to enforce referenced provisions of NRS Chapter 453 and NRS Chapter 639. NRS 639.070(l).

FACTUAL ALLEGATIONS

3. Respondent is currently registered by the Board to prescribe controlled substances. NRS 453.226. Such a registration authorizes the holder to write prescriptions for controlled substances. NRS 453.226.

4. A requirement of possessing a controlled substance registration with the Board is to maintain and actively use a prescription monitoring program (PMP) account. NRS 453.162.

5. Respondent's PMP account was activated on or about December 24, 2014.

6. On or about July 10, 2023, Board Inspector Jenine Davis worked with Respondent to update her PMP account.

7. Through this meeting, Board Inspector Davis noticed that Respondent was not in compliance with NRS 453.164(7) and NRS 639.23507.

8. Board Inspector Davis informed Board PMP Compliance Coordinator Dave Jones of this noncompliance.

9. Board PMP Compliance Coordinator Jones conducted an audit of Respondent's account to see whether or not they are compliant with state law related to the PMP. The audits are conducted to ensure compliance with NRS 453.164(7) and NRS 639.23507.

10. Board PMP Compliance Coordinator Jones found that Respondent had not conducted a "MyRx" review of all the prescriptions Respondent had written as required by NRS 453.164(7) for the entire calendar years of 2016, 2017, 2018, 2019, 2020, 2021, 2022, and 2023.

11. Respondent was also found to have only conducted one "MyRx" review ever, on April 29, 2015.

12. Board PMP Compliance Coordinator Jones also found that Respondent conducted individual patient queries as required by NRS 639.23507 a total of 83 times for 37 unique patients between the dates of January 1, 2018, and July 10, 2023.

13. Between January 1, 2018, and July 10, 2023, Respondent had written at least 4,444 prescriptions for controlled substances to at least 499 unique patients.

14. This means that Respondent failed to conduct individual patient inquires at least over 400 times during this period.

15. Respondent's PMP registration listed "jrivera022300@gmail.com" as the email address of record for Respondent's PMP account. Another email address associated with the PMP account was "chw.frontoffice@lvcoxmail.com."

APPLICABLE LAW

16. Each practitioner who is authorized to write prescriptions for human consumption of controlled substances listed in schedule II, III, IV or V shall access the database of the (PMP) program at least once every 6 months to review the information concerning the practitioner that is listed in the database, including, without limitation, information concerning prescriptions issued by the practitioner, and notify the Board if any such information is not correct, and to verify to the Board that he or she continues to have access to and has accessed the database as required by this subsection. NRS 453.164(7).

17. A practitioner shall, before issuing an initial prescription for a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the computerized program established by the Board. NRS 639.23507.

18. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

19. The Board may suspend or revoke any registration if the holder or applicant has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit. NRS 639.210(12).

20. The Board requires practitioners to properly register delegates prior to allowing the delegate access to the PMP. NAC 453.070.

21. Unprofessional conduct includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

22. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct and Violation of State Law – Failure to Query PMP Every 6 Months

23. Respondent established his PMP account on December 24, 2014. Between these dates, Respondent failed to review his PMP account every six (6) months for the entire calendar years of 2016, 2017, 2018, 2019, 2020, and 2021, 2022, and 2023 to ensure that the information in the account concerning the practitioner, including the legitimacy or validity of the prescriptions Respondent is shown as having written was correct. Respondent conducted a "MyRx" query of all the prescriptions she had written only one time ever, on April 29, 2015. Respondent was and is still required to do so every six (6) months. NRS 453.164(7).

24. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

25. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to query his PMP account every six (6) months to review the information in the account regarding the practitioner as is required by law for the calendar years of 2016, 2017, 2018, 2019, 2020, and 2021, 2022, and 2023. *See* NRS 453.164(7) and NAC 639.945(1)(i). The information regarding the practitioner that Respondent was and still is required to look at includes information concerning the prescriptions written by the practitioner. *See* NRS 453.164(7). A check of the PMP account at least once every six (6) months ensures that a practitioner has not had their credentials stolen or duplicated and that, if they

have been stolen or duplicated, the Board is notified of any potentially forged prescriptions by the practitioner in a timely manner. *See* NRS 453.164(7). The required six (6) month check of a practitioner's PMP account guards against forged controlled substance prescriptions and allows practitioners to work with the Board to stop them in real time. *See* NRS 453.164(7).

26. Respondent's actions and/or lack thereof has also violated Nevada law. NRS 639.210(12). Respondent's actions violated Nevada law because Respondent failed to comply with NRS 453.164(7) which requires a review of their "MyRx" history at least once every 6 months. *See* NRS 639.210(12). Respondent failed to comply with this statute during the dates referenced in the previous paragraph. *See* NRS 639.210(12).

27. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945.

COUNT TWO

Unprofessional Conduct and Violation of State Law – Failure to Query Patients Prior to Issuing an Initial Prescription for a Controlled Substance

28. Between the period of time from January 1, 2018, to July 10, 2023, Respondent only queried individual patients given unique prescriptions 83 times. During the same period, Respondent wrote over 4,400 prescriptions for controlled substances to at least 499 unique patients. Respondent failed to query the PMP regarding individual patient information when prescribing them controlled substances at least 400 times.

29. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

30. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to conduct patient queries on at least 400 patients given initial prescriptions for controlled substances in schedule I-IV, or for an opioid that is a controlled substance and listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance. *See* NRS 639.23507 and NAC 639.945(1)(i). Respondent failed to query at least 54 patients that should have been queried as PMP records reflect that Respondent only queried seven (7) patients since Respondent's PMP account has been active. *See* NRS 639.23507.

31. Respondent's actions and/or lack thereof has also violated Nevada law. NRS 639.210(12). Respondent's actions violated Nevada law because Respondent failed to comply with NRS 639.23507 which requires individual patient queries prior to prescribing new prescriptions for controlled substances and/or every 90 days thereafter for the duration of the treatment. *See* NRS 639.210(12). Respondent failed to comply with this statute during the dates referenced in the previous paragraph at least 400 times. *See* NRS 639.210(12).

32. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945.

COUNT THREE
Unprofessional Conduct and Violation of State Law– Allowing Unauthorized Access to PMP Account

33. Respondent's PMP registration listed "jrivera022300@gmail.com" as the email address of record for Respondent's PMP account. Another email address associated with the PMP account was "chw.frontoffice@lvcoxmail.com." Both email addresses are clearly not private email addresses for Respondent Tamara Beeghly.

34. 26. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

35. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent allowed access to the database to individuals that were not herself. NRS 453.164(8)(a).

36. Respondent's actions and/or lack thereof has also violated Nevada law. NRS 639.210(12). Respondent's actions violated Nevada law because Respondent failed to comply with NRS 453.164(8)(a) which maintains that information from the PMP is confidential. Respondent failed to comply with this statute because she allowed other members of her office to have access to the PMP without properly registering them as a delegate. *See* NRS 639.210(12); NAC 453.070.

37. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 17th day of JUNE 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TAMMARA BEEGHLY, PA,** **Certificate of Registration No. CS12793,** **Respondent.**	**CASE NO. 23-274-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 17th day of JUNE 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TAMMARA BEEGHLY, PA,** **Certificate of Registration No. CS12793,** **Respondent.**	**Case No. 23-274-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

TAMMARA BEEGHLY, PA

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of June 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Tammara Beeghly, PA
[redacted] W Sunset Road, Suite [redacted]
Las Vegas, NV 89148

Tammara Beeghly, PA
[redacted] E Flamingo Rd., # [redacted]
Las Vegas, NV 89119

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

JOSEPH S. GILBERT, ESQ.- SBN #. 9033
Joey Gilbert Law
405 Marsh Avenue
Reno, Nevada 89509
Telephone: (775) 284-7700
Attorney for Respondent

FILED
JUL 16 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, TAMMARA BEEGHLY, PA, Certificate of Registration No. CS12793 Respondent.	Case No.: 23-274-CS-S **ANSWER AND NOTICE OF DEFENSE**

COMES NOW, Respondent, TAMMARA BEEGHLY, PA (hereinafter referred to as "Respondent") by and through her counsel of record, JOSEPH S. GILBERT, ESQ. of JOEY GILBERT LAW, and answers the Notice of Intended Action and Accusation filed on June 17, 2024 as follows:

JURISDICTION

1. Responding to Paragraph 1 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has personal jurisdiction over Respondent Tammara Beeghly P.A.

2. Responding to Paragraph 2 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has jurisdiction over the subject matter of this accusation.

FACTUAL ALLEGATIONS

3. Responding to Paragraph 3 of the Notice of Intended Action and Accusation, Respondent admits to the allegations.

4. Responding to Paragraph 4 of the Notice of Intended Action and Accusation, Respondent admits to the allegations.

5. Responding to Paragraph 5 of the Notice of Intended Action and Accusation, Respondent admits to the allegations.

6. Responding to Paragraph 6 of the Notice of Intended Action and Accusation, Respondent admits to the allegations.

7. Responding to Paragraph 7 of the Notice of Intended Action and Accusation, Respondent is without knowledge sufficient so as to admit or deny the allegations, and as such denies said allegations.

8. Responding to Paragraph 8 of the Notice of Intended Action and Accusation, Respondent is without knowledge sufficient so as to admit or deny the allegations, and as such denies said allegations.

9. Responding to Paragraph 9 of the Notice of Intended Action and Accusation, Respondent is without knowledge sufficient so as to admit or deny the allegations, and as such denies said allegations.

10. Responding to Paragraph 10 of the Notice of Intended Action and Accusation, Respondent is without knowledge sufficient so as to admit or deny the allegations, and as such denies said allegations.

11. Responding to Paragraph 11 of the Notice of Intended Action and Accusation, Respondent is without knowledge sufficient so as to admit or deny the allegations as she does not

have any recollection of conducting the "MyRx" review in 2015, and as such denies said allegations.

12. Responding to Paragraph 12 of the Notice of Intended Action and Accusation, Respondent is without knowledge sufficient so as to admit or deny the total number of patient queries conducted pursuant to NRS 639.23507, and as such denies said allegations.

13. Responding to Paragraph 13 of the Notice of Intended Action and Accusation, Respondent is without knowledge sufficient so as to admit or deny the total number of prescriptions written and as such denies said allegations.

14. Responding to Paragraph 14 of the Notice of Intended Action and Accusation, Respondent is without knowledge sufficient so as to admit or deny the total number of individual patient inquiries conducted and as such denies said allegations.

15. Responding to Paragraph 15 of the Notice of Intended Action and Accusation, Respondent admits to the allegations.

APPLICABLE LAW

16. This Paragraph contains no allegations. Respondent acknowledges this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against Respondent, Respondent denies the same.

17. This Paragraph contains no allegations. Respondent acknowledges this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against Respondent, Respondent denies the same.

18. This Paragraph contains no allegations. Respondent acknowledges this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against Respondent, Respondent denies the same.

19. This Paragraph contains no allegations. Respondent acknowledges this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against Respondent, Respondent denies the same.

20. This Paragraph contains no allegations. Respondent acknowledges this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against Respondent, Respondent denies the same.

21. This Paragraph contains no allegations. Respondent acknowledges this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against Respondent, Respondent denies the same.

22. This Paragraph contains no allegations. Respondent acknowledges this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against Respondent, Respondent denies the same.

COUNT ONE

Unprofessional Conduct and Violation of State Law - Failure to Query PMP Every 6 Months

23. Responding to Paragraph 23 of the Notice of Intended Action and Accusation, Respondent admits that her PMP account was established on December 24, 2014. Respondent denies the remaining allegations therein.

24. Responding to Paragraph 24 of the Notice of Intended Action and Accusation, Respondent denies engaging in unprofessional conduct under NRS 639.210(4) and denies performing her duties in an incompetent, unskillful, or negligent manner under NAC 639.945(1)(i).

25. Responding to Paragraph 25 of the Notice of Intended Action and Accusation, Respondent denies the allegation that she failed to query her PMP account.

26. Responding to Paragraph 26 of the Notice of Intended Action and Accusation, Respondent denies that her actions violated Nevada law under NRS 639.210(12).

27. Responding to Paragraph 27 of the Notice of Intended Action and Accusation, Respondent denies that her actions constitute unprofessional conduct or a violation of Nevada law.

COUNT TWO

Unprofessional Conduct and Violation of State Law - Failure to Query Patients Prior to Issuing an Initial Prescription for a Controlled Substance

28. Responding to Paragraph 28 of the Notice of Intended Action and Accusation, Respondent denies the allegations.

29. Responding to Paragraph 29 of the Notice of Intended Action and Accusation, Respondent denies engaging in unprofessional conduct and denies performing her duties in an incompetent, unskillful, or negligent manner under NAC 639.945(1)(i).

30. Responding to Paragraph 30 of the Notice of Intended Action and Accusation, Respondent denies engaging in unprofessional conduct and denies performing her duties in an incompetent, unskillful, or negligent manner.

31. Responding to Paragraph 31 of the Notice of Intended Action and Accusation, Respondent denies the allegations.

32. Responding to Paragraph 32 of the Notice of Intended Action and Accusation, Respondent denies the allegations.

COUNT THREE

Unprofessional Conduct and Violation of State Law - Allowing Unauthorized Access to PMP Account

33. Responding to Paragraph 33 of the Notice of Intended Action and Accusation, Respondent admits that her PMP registration listed "jrivera022300@gmail.com" and "chw.frontoffice@lvcoxmail.com" as associated email addresses, which were used solely for professional purposes only.

34. Responding to Paragraph 34 of the Notice of Intended Action and Accusation, Respondent denies engaging in unprofessional conduct under NRS 639.210(4) and denies

performing her duties in an incompetent, unskillful, or negligent manner under NAC 639.945(1)(i).

35. Responding to Paragraph 35 of the Notice of Intended Action and Accusation, Respondent denies the allegations.

36. Responding to Paragraph 36 of the Notice of Intended Action and Accusation, Respondent denies the allegations.

37. Responding to Paragraph 37 of the Notice of Intended Action and Accusation, Respondent denies the allegations that she engaged in unprofessional conduct.

WHEREFORE, Respondent respectfully submits this response to the Notice of Intended Action and Accusation. Respondent, Tammara Beeghly, PA, by and through her counsel of record, Joseph S. Gilbert, Esq. of Joey Gilbert Law, asserts that she has consistently met her professional obligations. She has completed her Continuing Medical Education (CME) requirements every year, renewed her license, and paid her dues without any reminders regarding the status of her Prescription Monitoring Program (PMP) account. Respondent remains committed to upholding the highest standards of professional conduct and compliance with all applicable laws and regulations.

DATED this 15th day of July, 2024.

JOEY GILBERT LAW

JOSEPH S. GILBERT, ESQ.
Attorney for Respondent,

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 15th day of July, 2024.

Tammara Beeghly PA

TAMMARA BEEGHLY, PA

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **Answer and Notice of Defense** was served upon the following person by electronic transmission and/or by mailing a copy to their last known address, first class mail, postage prepaid for non-registered users, on this 15th day of July, 2024 as follows:

Nevada Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521
Email: TeamBC@pharmacy.nv.gov and zunino@pharmacy.nv.gov

DATED this 15th day of July, 2024.

JOEY GILBERT LAW

Nancy Vazquez

Nancy Vazquez, Legal Assistant

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TAMMARA BEEGHLY, PA,** **Certificate of Registration Nos. CS12793,** **Respondent.**	**Case No. 23-274-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Gregory L. Zunino, Esq., and Respondent Tammara Beeghly, PA ("Respondent"), by and through counsel, Joey Gilbert, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy (the "Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that she understands the terms of this Stipulation and Order ("Stipulation") and has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives her right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One and Count Two of the Accusation. In this regard, Respondent admits that between 2016 and 2023, she did not access the prescription monitoring program database for the purpose of reviewing her prescribing activity, as required by NRS 453.164(7), and she did not review patient utilization reports in instances where such review was required pursuant to NRS 639.23507.

7. The parties agree that there is no direct evidence to establish that Respondent allowed unauthorized persons to access the prescription monitoring program database using Respondent's credentials. Therefore, in the interest of compromise, Count Three of the Accusation shall be dismissed upon approval of this Stipulation by the Board.

8. Respondent represents that she has read and is familiar with the provisions of NRS 453.164(7) and NRS 639.23507 concerning the use of, and access to, the prescription monitoring program database, and has educated herself on the proper use of said database.

9. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the parties agree to the imposition of the following penalties as to the violations alleged in Count One and Count Two of the Accusation, to wit:

A. Respondent accepts this Stipulation as a public reprimand issued pursuant to NRS 639.255(1)(e).

B. Respondent shall pay an administrative fine of **Two Thousand Five Hundred and 00/100 Dollars ($2,500.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

C. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**"

Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before October 15, 2024.

10. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 23-274-CS-S. However, Respondent understands and acknowledges that her failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

11. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

12. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60. If approved, this Stipulation shall become effective as of the date upon which the Board enters its written order below.

13. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Stipulation.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 5th day of August 2024.

Tammara Beeghly P.A.
TAMMARA BEEGHLY, PA
Certificate of Registration No. CS12793

Signed this 8th day of August 2024.

GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

APPROVED AS TO FORM:

JOEY GILBERT, ESQ.
Nevada Bar No. 9033

ORDER

As to Respondent Tammara Beeghly, PA, in Case No. 23-274-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of September 2024.

Helen Park, President
Nevada State Board of Pharmacy

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FILED
JUL 24 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #06424, Pharmacy License No. PH01628, and** **SANETTE SEVERANCE, RPH, Certificate of Registration No. 20772,** **Respondents.**	**Case Nos. 23-310-PH-S** **23-310-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Pharmacist Sanette Severance (RPH Severance) because RPH Severance is registered by the Board to practice pharmacy in Nevada. RPH Severance has held Certificate of Registration No. 20772 since January 20, 2021. RPH Severance has not previously been disciplined by the Board.

2. The Board has personal jurisdiction over Walgreens Pharmacy #06424 (Walgreens), because Walgreens holds Pharmacy License No. PH01628, issued by the Board pursuant to NRS 639.230. Walgreens has held Pharmacy License No. PH01628 since August 21, 2001. On March 12, 2024, the Board issued a citation to Walgreens concerning a dispensing error committed by a pharmacist other than RPH Severance. Walgreens paid the applicable $500 fine.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of dangerous drugs and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. Walgreens operates a pharmacy on West Horizon Ridge Parkway in Henderson, Nevada. In August 2023, Walgreens employed RPH Severance as a staff pharmacist at that pharmacy location.

5. On or about August 8, 2023, patient G.J. arrived at the pharmacy before his prescription was ready for pick-up. RPH Severance filled the prescription for patient G.J. while he waited.

6. Patient G.J.'s health care provider had prescribed cough syrup with codeine, specifically codeine-guaifenesin. This was a new prescription for patient G.J., such that it required patient G.J. to be counseled by a pharmacist before the sale.

7. As she began to fill the prescription, RPH Severance noted that the prescription called for 560ml of cough syrup. This was too large of a quantity to be dispensed in a single store bottle.

8. To save time while patient G.J waited for his prescription, RPH Severance dispensed a portion of the codeine syrup in the manufacturer's stock bottle and poured the balance of the prescription into a store bottle.

9. RPH Severance affixed a label with instructions to each of the bottles. The stock bottle was also labeled with the manufacturer's instructions for use. The two bottles were enclosed in a bag before being delivered to patient G.J.

10. Before delivering the bag to patient G.J., RPH Severance asked patient G.J. whether he had any questions about his new prescription. Patient G.J. stated that he had no questions, and he left the pharmacy with the bag containing two bottles of codeine cough syrup.

11. Aside from asking whether patient G.J. had any questions, RPH Severance communicated no information to patient G.J. concerning his prescription for codeine-guaifenesin, its use, possible side effects, drug interactions, or contraindications.

12. After patient G.J. left the pharmacy, RPH Severance made an entry in pharmacy records indicating that she had counseled patient G.J. concerning his prescription for codeine-guaifenesin.

13. When, at home, patient G.J. opened his prescription bag and discovered two bottles of medication, he mistakenly concluded that he had received two different kinds of medication. Patient G.J. found it confusing that one of the bottles was labeled with two sets of instructions.

14. Concerned by an apparent lack of professionalism by Walgreens and/or RPH Severance, patient G.J.'s spouse made a complaint to the Board.

APPLICABLE LAW

15. The Board may discipline the holder of a license or registration issued by the Board if the holder engages in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

16. Unprofessional conduct includes performing one's duties as the holder of a certificate or registration issued by the Board in an "incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

17. A pharmacist is required to communicate with the patient or a person caring for the patient all matters that will enhance therapy through drugs. NRS 639.266(1). The communication must include appropriate elements of counseling for the patient, as established by the Board. NRS 639.266(1).

18. A pharmacist has a duty to counsel patients and supply all information required by the Board pursuant to NAC 639.707. The information may include, among other things, the name and a description of the drug, the form of dosage, dose, route of administration and duration of drug therapy, the intended use of the drug or device and expected responses from that use, and any common severe side effects, interactions and contraindications that may occur, and recommendations to avoid these side effects, interactions or contraindications, and the action required if they occur. *Id.*

19. A pharmacist has a duty to keep accurate records of whether counseling was given to or refused by a patient. *See* NAC 639.707(6).

20. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of its employees. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

COUNT ONE
Failure by Pharmacist to Counsel
(RPH Severance and Walgreens)

21. Although RPH Severance asked patient G.J. if he had any questions about his medication, RPH Severance failed to communicate matters which would enhance therapy through drugs. Nevada law requires a pharmacist to affirmatively counsel a patient by communicating all matters which will enhance therapy through drugs. Nevada law explicitly lists many of the subjects that a pharmacist should address when counseling a patient. *See* NRS 639.266(1) and NAC 639.707(2). RPH Severance did not discuss a single relevant topic with patient G.J.

22. Having neglected to counsel patient G.J. in a manner that enhances drug therapy, RPH Severance performed her duties in an incompetent, unskillful or negligent manner. This constitutes unprofessional conduct for which RPH Severance may be disciplined. NRS 639.210(4); NAC 639.945(1)(i).

23. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Walgreens is responsible for those violations, including all errors and omissions of RPH Severance. NRS 639.230(5), NAC 639.702, and NAC 639.945(2).

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COUNT TWO

Failure to Make an Accurate Record of Counseling
(RPH Severance and Walgreens)

24. RPH Severance made an entry in pharmacy records indicating that patient G.J. had been counseled even though she did not properly counsel him. Counseling records should only indicate that a patient has been counseled if the patient was counseled properly. *See* NAC 639.707(6). In this case, patient G.J. was not properly counseled.

25. Having made a false, misleading, or incomplete record of counseling, RPH Severance performed her duties in an incompetent, unskillful or negligent manner. This constitutes unprofessional conduct for which RPH Severance may be disciplined. NRS 639.210(4); NAC 639.945(1)(i).

26. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Walgreens is responsible for those violations, including all errors and omissions of RPH Severance. NRS 639.230(5), NAC 639.702, and NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Sanette Severance and the pharmacy license of Respondent Walgreens Pharmacy #06424.

DATED this 24th day of JULY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #06424,** **Pharmacy License No. PH01628,** **Respondent.**	**CASE NO. 23-310-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #06424, Pharmacy License No. PH01628,** **Respondent.**	**Case No. 23-310-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR
Walgreen's Pharmacy #06424

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of July 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

WALGREENS #06424
c/o William Stilling, Esq
222 South Main St., Suite 500
Salt Lake City, UT 84101

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #06424, Pharmacy License No. PH01628, and** **SANETTE SEVERANCE, RPH, Certificate of Registration No. 20772,** **Respondents.**	**Case Nos. 23-310-PH-S** **23-310-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Pharmacist Sanette Severance (RPH Severance) because RPH Severance is registered by the Board to practice pharmacy in Nevada. RPH Severance has held Certificate of Registration No. 20772 since January 20, 2021. RPH Severance has not previously been disciplined by the Board.

2. The Board has personal jurisdiction over Walgreens Pharmacy #06424 (Walgreens), because Walgreens holds Pharmacy License No. PH01628, issued by the Board pursuant to NRS 639.230. Walgreens has held Pharmacy License No. PH01628 since August 21, 2001. On March 12, 2024, the Board issued a citation to Walgreens concerning a dispensing error committed by a pharmacist other than RPH Severance. Walgreens paid the applicable $500 fine.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of dangerous drugs and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. Walgreens operates a pharmacy on West Horizon Ridge Parkway in Henderson, Nevada. In August 2023, Walgreens employed RPH Severance as a staff pharmacist at that pharmacy location.

5. On or about August 8, 2023, patient G.J. arrived at the pharmacy before his prescription was ready for pick-up. RPH Severance filled the prescription for patient G.J. while he waited.

6. Patient G.J.'s health care provider had prescribed cough syrup with codeine, specifically codeine-guaifenesin. This was a new prescription for patient G.J., such that it required patient G.J. to be counseled by a pharmacist before the sale.

7. As she began to fill the prescription, RPH Severance noted that the prescription called for 560ml of cough syrup. This was too large of a quantity to be dispensed in a single store bottle.

8. To save time while patient G.J waited for his prescription, RPH Severance dispensed a portion of the codeine syrup in the manufacturer's stock bottle and poured the balance of the prescription into a store bottle.

9. RPH Severance affixed a label with instructions to each of the bottles. The stock bottle was also labeled with the manufacturer's instructions for use. The two bottles were enclosed in a bag before being delivered to patient G.J.

10. Before delivering the bag to patient G.J., RPH Severance asked patient G.J. whether he had any questions about his new prescription. Patient G.J. stated that he had no questions, and he left the pharmacy with the bag containing two bottles of codeine cough syrup.

11. Aside from asking whether patient G.J. had any questions, RPH Severance communicated no information to patient G.J. concerning his prescription for codeine-guaifenesin, its use, possible side effects, drug interactions, or contraindications.

12. After patient G.J. left the pharmacy, RPH Severance made an entry in pharmacy records indicating that she had counseled patient G.J. concerning his prescription for codeine-guaifenesin.

13. When, at home, patient G.J. opened his prescription bag and discovered two bottles of medication, he mistakenly concluded that he had received two different kinds of medication. Patient G.J. found it confusing that one of the bottles was labeled with two sets of instructions.

14. Concerned by an apparent lack of professionalism by Walgreens and/or RPH Severance, patient G.J.'s spouse made a complaint to the Board.

APPLICABLE LAW

15. The Board may discipline the holder of a license or registration issued by the Board if the holder engages in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

16. Unprofessional conduct includes performing one's duties as the holder of a certificate or registration issued by the Board in an "incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

17. A pharmacist is required to communicate with the patient or a person caring for the patient all matters that will enhance therapy through drugs. NRS 639.266(1). The communication must include appropriate elements of counseling for the patient, as established by the Board. NRS 639.266(1).

18. A pharmacist has a duty to counsel patients and supply all information required by the Board pursuant to NAC 639.707. The information may include, among other things, the name and a description of the drug, the form of dosage, dose, route of administration and duration of drug therapy, the intended use of the drug or device and expected responses from that use, and any common severe side effects, interactions and contraindications that may occur, and recommendations to avoid these side effects, interactions or contraindications, and the action required if they occur. *Id.*

19. A pharmacist has a duty to keep accurate records of whether counseling was given to or refused by a patient. *See* NAC 639.707(6).

20. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of its employees. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

COUNT ONE
Failure by Pharmacist to Counsel
(RPH Severance and Walgreens)

21. Although RPH Severance asked patient G.J. if he had any questions about his medication, RPH Severance failed to communicate matters which would enhance therapy through drugs. Nevada law requires a pharmacist to affirmatively counsel a patient by communicating all matters which will enhance therapy through drugs. Nevada law explicitly lists many of the subjects that a pharmacist should address when counseling a patient. *See* NRS 639.266(1) and NAC 639.707(2). RPH Severance did not discuss a single relevant topic with patient G.J.

22. Having neglected to counsel patient G.J. in a manner that enhances drug therapy, RPH Severance performed her duties in an incompetent, unskillful or negligent manner. This constitutes unprofessional conduct for which RPH Severance may be disciplined. NRS 639.210(4); NAC 639.945(1)(i).

23. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Walgreens is responsible for those violations, including all errors and omissions of RPH Severance. NRS 639.230(5), NAC 639.702, and NAC 639.945(2).

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COUNT TWO
Failure to Make an Accurate Record of Counseling
(RPH Severance and Walgreens)

24. RPH Severance made an entry in pharmacy records indicating that patient G.J. had been counseled even though she did not properly counsel him. Counseling records should only indicate that a patient has been counseled if the patient was counseled properly. *See* NAC 639.707(6). In this case, patient G.J. was not properly counseled.

25. Having made a false, misleading, or incomplete record of counseling, RPH Severance performed her duties in an incompetent, unskillful or negligent manner. This constitutes unprofessional conduct for which RPH Severance may be disciplined. NRS 639.210(4); NAC 639.945(1)(i).

26. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Walgreens is responsible for those violations, including all errors and omissions of RPH Severance. NRS 639.230(5), NAC 639.702, and NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Sanette Severance and the pharmacy license of Respondent Walgreens Pharmacy #06424.

DATED this 24th day of JULY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SANETTE SEVERANCE, RPH,** **Certificate of Registration No. 20772,** **Respondent.**	**CASE NO. 23-310-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SANETTE SEVERANCE, RPH,** **Certificate of Registration No. 20772,** **Respondent.**	**Case No. 23-310-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

SANETTE SEVERANCE, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of July 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sanette Severance, RPH
[redacted] Village Walk Dr., #[redacted]
Henderson, NV 89012

Sanette Severance, RPH
c/o WALGREENS
11001 S. Eastern Ave.
Henderson, NV 89052

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
MAR 2 2 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NANA KUFUOR, MD,** **Certificate of Registration No. CS09587,** **Respondent.**	**Case No. 23-341-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Nana Kufuor, M.D. (Respondent), because the violations alleged herein, weigh on Respondent's character to hold a certificate of registration issued by the Board pursuant to NRS 453.226, authorizing Respondent to write prescriptions for controlled substances. Since August 12, 1999, Respondent has held certificate of registration no. CS09587, allowing Respondent to prescribe controlled substances issued by the Board pursuant to NRS 453.226.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent has been registered by the Board to prescribe controlled substances since August 12, 1999. NRS 453.226. Such a registration authorizes the holder to write prescriptions for controlled substances. NRS 453.226.

4. A requirement of possessing a controlled substance registration with the Board is to maintain and actively use a prescription monitoring program (PMP) account. NRS 453.162.

5. Respondent's PMP account was activated on or about February 8, 2017.

6. Board PMP Compliance Coordinator Dave Jones conducts audits of practitioners to ensure that they are compliant with state law related to the PMP. The audits are conducted to ensure compliance with NRS 453.164(7) and NRS 639.23507.

7. Board PMP Compliance Coordinator Jones conducted an audit of Respondent's PMP account.

8. Board PMP Compliance Coordinator Jones found that Respondent had never conducted a six-month "MyRx" review of all the prescriptions Respondent had written as required by NRS 453.164(7). Respondent never reviewed the PMP every six (6) months for the entire calendar years of 2017, 2018, 2019, 2020, 2021, 2022, and 2023.

9. Board PMP Compliance Coordinator Jones also found that Respondent conducted individual patient queries as required by NRS 639.23507 a grand total of three (3) times between the dates of January 1, 2018, and August 14, 2023.

10. Between January 1, 2018, and August 8, 2023, Respondent had written over 500 prescriptions for controlled substances to over 70 unique patients.

11. This means that Respondent failed to conduct individual patient inquires at least over 70 times during this period.

12. Prescriptions for controlled substances are required to be sent in an electronic format to a pharmacy. NRS 639.23535.

13. The Board ceased granting waivers to practitioners that would allow them to transmit prescriptions for controlled substances via other means. All waivers ended on January 1, 2022.

14. Respondent, on information and belief, continued and/or continues to transmit prescriptions for controlled substances via paper prescription pad.

15. From January 1, 2022, to August 8, 2023, Respondent wrote at least forty-five (45) prescriptions for controlled substances to at least thirteen (13) unique patients via paper prescription pad.

APPLICABLE LAW

16. Each practitioner who is authorized to write prescriptions for human consumption of controlled substances listed in schedule II, III, IV or V shall access the database of the (PMP) program at least once every 6 months to review the information concerning the practitioner that is listed in the database, including, without limitation, information concerning prescriptions issued by the practitioner, and notify the Board if any such information is not correct, and to verify to the Board that he or she continues to have access to and has accessed the database as required by this subsection. NRS 453.164(7).

17. A practitioner shall, before issuing an initial prescription for a controlled substance listed in schedule II, lII or IV or an opioid that is a controlled substance listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the computerized program established by the Board. NRS 639.23507.

18. Prescriptions for controlled substances are required to be sent in an electronic format to a pharmacy. NRS 639.23535.

19. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

20. Unprofessional conduct includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

21. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Failure to Query PMP Every 6 Months

22. Respondent established his PMP account on February 8, 2017. Between these dates, Respondent failed to review his PMP account every six (6) months for the entire calendar years of 2017, 2018, 2019, 2020, and 2021, 2022, 2023 to ensure that the information in the account concerning

the practitioner, including the legitimacy or validity of the prescriptions Respondent is shown as having written was correct. Respondent was and is still required to do so every six (6) months. NRS 453.164(7).

23. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

24. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to query his PMP account every six (6) months to review the information in the account regarding the practitioner as is required by law for the calendar years of 2017, 2018, 2019, 2020, and 2021, 2022, and 2023. *See* NRS 453.164(7) and NAC 639.945(1)(i). The information regarding the practitioner that Respondent was and still is required to look at includes information concerning the prescriptions written by the practitioner. *See* NRS 453.164(7). A check of the PMP account at least once every six (6) months ensures that a practitioner has not had their credentials stolen or duplicated and that, if they have been stolen or duplicated, the Board is notified of any potentially forged prescriptions by the practitioner in a timely manner. *See* NRS 453.164(7). The required six (6) month check of a practitioner's PMP account guards against forged controlled substance prescriptions and allows practitioners to work with the Board to stop them in real time. *See* NRS 453.164(7).

25. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

COUNT TWO

Unprofessional Conduct – Failure to Query Patients Prior to Issuing an Initial Prescription for a Controlled Substance

26. Between the period of time from January 1, 2018, to August 8, 2023, Respondent only queried individual patients given unique prescriptions three (3) times. During the same period, Respondent wrote over 500 prescriptions for controlled substances to over seventy (70) unique patients. Respondent failed to query the PMP regarding individual patient information when prescribing them controlled substances at least seventy (70) times.

27. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

28. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to conduct patient queries on at least seventy (70) patients given initial prescriptions for controlled substances in schedule I-IV, or for an opioid that is a controlled substance and listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance. *See* NRS 639.23507 and NAC 639.945(1)(i). Respondent failed to query at least seventy (70) patients that should have been queried as PMP records reflect that Respondent only queried three (3) patients since Respondent's PMP account has been active. *See* NRS 639.23507.

29. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945

COUNT THREE

Unprofessional Conduct – Failure to Transmit Prescriptions for Controlled Substances in an Electronic Format

30. A practitioner is required to transmit prescriptions for controlled substances via electronic transmission. NRS 639.23535. Since January 1, 2022, all exemptions given by the Board

from this electronic transmission requirement have expired. The Board no longer offers exemptions from the electronic transmission program. Since January 1, 2022, Respondent has written at least forty-five (45) prescriptions for controlled substances to at least thirteen (13) unique patients.

31. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

32. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because he continued to write prescriptions for controlled substances via paper prescription pad despite having no valid statutory reason to do so and all exemptions from the electronic transmission requirement having expired. *See* NRS 639.23535.

33. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 22nd day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NANA KUFUOR, MD,** **Certificate of Registration No. CS09587,** **Respondent.**	**Case No. 23-341-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NANA KUFUOR, MD,** **Certificate of Registration No. CS09587** **Respondent.**	**Case No. 23-341-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

NANA KUFUOR, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of March 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Nana Kufuor, MD
[redacted] Sudley Court
Las Vegas, NV 89145

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

6

6A

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Email: Pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

March 12, 2024

VIA CERTIFIED/REGULAR U.S. MAIL & EMAIL
Heath G. DeHart, P.A. (CS33956)
[redacted]A Street
Hawthorne, NV 89415
Email: [redacted]

CITATION-AND-FINE: Case No. 22-351-CS-N – Unlicensed Prescribing Activity in Nevada

Dear P.A. DeHart:

The Nevada State Board of Pharmacy (Board) has determined that between January 10, 2022, and June 3, 2022, you issued six (6) prescriptions for controlled substances, including prescriptions for Tramadol and Acetaminophen-Codeine. These prescriptions were written for approximately six (6) Nevada-based patients. During the above time frame, you had applied for, but had not yet received a Nevada certificate of registration to prescribe controlled substances. The processing of your application was delayed because you did not submit proof of a registration number issued to you by the federal Drug Enforcement Administration.

In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. NRS 453.056. Every practitioner who intends to prescribe controlled substances in Nevada must first apply for and obtain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who prescribes controlled substances without having obtained a Nevada certificate of registration is potentially subject to criminal and/or civil penalties for prescribing controlled substances in Nevada without authorization. NRS 453.232; NRS 453.553; NRS 453.5531; NRS 639.100(1).

In light of the foregoing, this letter shall serve as a **CITATION** pursuant to NRS 639.2895(2) for prescribing controlled substances without having obtained the required certificate of registration issued by the Board. Based on the above evidentiary summary, the Board has assessed an **administrative fine** against you in the amount of **Five Thousand and 00/100 Dollars ($5,000.00).**

If you do not intend to contest the above fine, please pay the fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an extension for good cause shown. Payment must be made by *certified check, cashier's check,* or *money order* payable to **"State of Nevada, Office of the Treasurer,"** and it must be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You may appeal this citation by submitting a notice of appeal requesting a public hearing before the Board. You must submit any such notice of appeal not later than 30 days after receipt of this citation. NRS 639.2895(2). Please mail or personally deliver any notice of appeal to the Reno address listed on the letterhead.

Pursuant to the Nevada Public Records Act, this citation constitutes a public record that must be released to anyone who makes a proper request for it. However, unless this citation is affirmed by the Board on appeal, this matter will not be reported to the National Practitioner Data Bank. If you have any questions, please contact the Board's Assistant General Counsel, Gustaf Vanderdonck, at 775-850-1440, ext. 132, or *via* email at gvanderdonck@pharmacy.nv.gov.

Sincerely,

Nevada State Board of Pharmacy

9171 9690 0935 0278 8414 01

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Email: Pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

March 13, 2024

VIA CERTIFIED/REGULAR U.S. MAIL & EMAIL
Heath G. DeHart, P.A. (CS33956)
[redacted] S 900 E
St George, UT 84790
Email: [redacted]

CITATION-AND-FINE: Case No. 22-351-CS-N – Unlicensed Prescribing Activity in Nevada

Dear P.A. DeHart:

The Nevada State Board of Pharmacy (Board) has determined that between January 10, 2022, and June 3, 2022, you issued six (6) prescriptions for controlled substances, including prescriptions for Tramadol and Acetaminophen-Codeine. These prescriptions were written for approximately six (6) Nevada-based patients. During the above time frame, you had applied for, but had not yet received a Nevada certificate of registration to prescribe controlled substances. The processing of your application was delayed because you did not submit proof of a registration number issued to you by the federal Drug Enforcement Administration.

In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. NRS 453.056. Every practitioner who intends to prescribe controlled substances in Nevada must first apply for and obtain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who prescribes controlled substances without having obtained a Nevada certificate of registration is potentially subject to criminal and/or civil penalties for prescribing controlled substances in Nevada without authorization. NRS 453.232; NRS 453.553; NRS 453.5531; NRS 639.100(1).

In light of the foregoing, this letter shall serve as a **CITATION** pursuant to NRS 639.2895(2) for prescribing controlled substances without having obtained the required certificate of registration issued by the Board. Based on the above evidentiary summary, the Board has assessed an **administrative fine** against you in the amount of **Five Thousand and 00/100 Dollars ($5,000.00).**

If you do not intend to contest the above fine, please pay the fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an extension for good cause shown. Payment must be made by *certified check, cashier's check,* or *money order* payable to **"State of Nevada, Office of the Treasurer,"** and it must be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You may appeal this citation by submitting a notice of appeal requesting a public hearing before the Board. You must submit any such notice of appeal not later than 30 days after receipt of this citation. NRS 639.2895(2). Please mail or personally deliver any notice of appeal to the Reno address listed on the letterhead.

Pursuant to the Nevada Public Records Act, this citation constitutes a public record that must be released to anyone who makes a proper request for it. However, unless this citation is affirmed by the Board on appeal, this matter will not be reported to the National Practitioner Data Bank. If you have any questions, please contact the Board's Assistant General Counsel, Gustaf Vanderdonck, at 775-850-1440, ext. 132, or *via* email at gvanderdonck@pharmacy.nv.gov.

Sincerely,

Nevada State Board of Pharmacy

9171 9690 0935 0278 8413 95

Heath DeHart
[redacted]
St. George, UT 84790
[redacted]
03/20/2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, suite 206
Reno, NV 89521

Subject: Appeal of Citation for Prescribing Controlled Substances
Heath G. DeHart, PA (CS33956) Case No. 22-351-CS-N

Dear Members of the Nevada Board of Pharmacy,

I am writing to appeal the decision to issue a citation to me, Heath Gabriel DeHart, Physician Assistant, for prescribing controlled substances between January 10, 2022, and June 3, 2022. I am a licensed physician assistant, and I believed that my prescribing authority for controlled substances had been transferred to fully approved status during the timeframe mentioned above.

As you are aware, I was initially approved under COVID-19 status, and my license was later converted to a fully approved physician assistant license. Unfortunately, I was not fully aware of the intricacies of Nevada State Board of Pharmacy approval process, and I mistakenly believed that my prescribing authority for controlled substances had also been transferred to fully approved status.

I want to emphasize that I did not intend to prescribe controlled substances without proper authorization or maliciously. My sole intention was to provide adequate pain management to patients who were experiencing traumatic injuries, or severe conditions causing pain. There was no monetary gain for me in prescribing these medications, and the only benefit was to ensure the well-being and comfort of my patients.

I deeply regret any misunderstanding , or oversight on my part. and I immediately took steps to rectify the situation and ensure compliance with all regulations and guidelines once I was made aware of the situation. I am committed to upholding the highest standards of healthcare and serving the people of Nevada with integrity and professionalism.

I respectfully request that you reconsider the decision to issue a citation to me and take into account the circumstances outlined in this appeal. I am willing to provide any additional information or documentation that may assist in your review of this matter.

Thank you for your attention to this appeal, and I look forward to a favorable resolution.

Sincerely,

Heath DeHart, PA-C

FILED
AUG 20 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 22-351-CS-N**
Petitioner,	)	
v.	)	
HEATH DEHART, PA,	)	**STIPULATED FACTS**
Certificate of Registration No. CS33956,	)	
Respondent.	)	

Gustaf Vanderdonck, Esq., General Counsel for Petitioner the Nevada State Board of Pharmacy (Board) and P.A. Heath DeHart, Certificate of Registration No. CS33956 (Respondent),

HEREBY STIPULATE AND AGREE THAT:

1. All factual allegations (Paragraphs 1-5) contained in the Statement to the Respondent and Notice of Hearing are true and accurate.

Respondent P.A. Heath DeHart has fully considered the factual allegations contained in the Statement to the Respondent and Notice of Hearing on file in this matter and these Stipulated Facts. He freely and voluntarily agrees to the factual statements set forth herein.

Signed this 20 day of August, 2024

Respondent Heath DeHart, P.A.
Certificate of Registration No. CS33956

Gustaf Vanderdonck, Esq.
General Counsel
Nevada State Board of Pharmacy

7

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☒ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☒ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Advantage Medical Supply, Inc

MDEG Physical Address: 350 Falcon Ridge Parkway Suite 103

City: Mesquite State: NV Zip: 89027

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 8882700202 Website: www.advantagehme.org

Email: support@advantagehme.org

Name of MDEG Administrator (NAC 639.694): Kolton Young

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions	☒ Medical Gases**
☐ Pharmacies[a]	☒ Respiratory Equipment**
☐ Practitioners[a]	☒ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☒ Assistive Equipment
☐ Wholesalers[a]	☒ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Jayden Nyman Telephone: 8015400189

Check the Days the Business will be Opened and provide the Hours of Operation				
☑ Mon: 9-5	☑ Tue: 9-5	☑ Wed: 9-5	☑ Thurs: 9-5	☑ Fri: 9-5
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
UT Medicaid: 870529529, ID Medicaid: 870529529, AZ Medicaid: 150279, Medicare: 0897950001, 1023726171,
1497463541, 1508594730, 1689392847, 1962120113

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: None Credentials: _____ %: _____

Name: None Credentials: _____ %: _____

Name: None Credentials: _____ %: _____

Name: None Credentials: _____ %: _____

Name: None Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Utah

Parent Company (if any): _____

Corporation/Organization Name: Advantage Medical Supply, Inc

Mailing Address: 590 Greenwood Drive

City: Brigham City State: UT Zip: 84302

Telephone: 4357340488 Email: kory@advantagehme.org, support@advantagehme.org

Contact Person Name: Kory Young

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located** outside of this State **must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kory Young

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

04/08/2024

Date

Board Use Only	Date Received: 4/15/24	Amount: $500 - Check #2941

Registered Principals

Name	Type	City	Status
ADVANTAGE MEDICAL SUPPLY, INC.	Corporation	BRIGHAM CITY	Active
Position	Name	Address	
Director	NO DIRECTOR PER STATUTE UCA SECT16-10A-732		
President	SHANE EVAN MEACHAM	[redacted]	SMITHFIELD UT 84335
Registered Agent	SHANE ~~MECHAM~~ MEACHAM	[redacted]	SMITHFIELD UT 84335
Vice President	KORY SPENCER YOUNG	[redacted]	KANAB UT 84741
If you believe there may be more principals, click here to View Filed Documents			

50%

50%

Business Name:

Give Feedback

Utah Department of Commerce
Division of Corporations & Commercial Code
160 East 300 South, 2nd Floor, PO Box 146705
Salt Lake City, UT 84114-6705
Service Center: (801) 530-4849
Toll Free: (877) 526-3994 Utah Residents
Fax: (801) 530-6438
Web Site: http://www.commerce.utah.gov

04/10/2024
1193035-014204102024-3188339

CERTIFICATE OF EXISTENCE

Registration Number:	1193035-0142
Business Name:	ADVANTAGE MEDICAL SUPPLY, INC.
Registered Date:	September 19, 1994
Entity Type:	Corporation - Domestic - Profit
Status:	Current

The Division of Corporations and Commercial Code of the State of Utah, custodian of the records of business registrations, certifies that the business entity on this certificate is authorized to transact business and was duly registered under the laws of the State of Utah. The Division also certifies that this entity has paid all fees and penalties owed to this state; its most recent annual report has been filed by the Division **(unless Delinquent)**; and, that Articles of Dissolution have not been filed.

L. Veillette

Leigh Veillette
Director
Division of Corporations and Commercial Code

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LIMITED LICENSE

Advantage Medical Supply, Inc

EFFECTIVE 09/30/2019

EXPIRATION 09/30/2025

REFERENCE NUMBER(S), CLASSIFICATION(S), & DETAIL(S):

5132186-1714 Pharmacy - Class E Business

Medical Gas Provider

DBA: None Associated

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

ADVANTAGE MEDICAL SUPPLY, INC
[redacted] GREENWOOD DR
BRIGHAM CITY UT 84302

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LIMITED LICENSE

EFFECTIVE DATE: 09/30/2019
EXPIRATION DATE: 09/30/2025
ISSUED TO: Advantage Medical Supply, Inc
[redacted] GREENWOOD DR
BRIGHAM CITY UT 84302

REFERENCE NUMBER(S) CLASSIFICATION(S) & DETAIL(S):
5132186-1714 Pharmacy - Class E Business
Medical Gas Provider

DBA: None Associated

Form #1

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LIMITED LICENSE

Advantage Medical Supply Inc

EFFECTIVE 12/01/2021

EXPIRATION 09/30/2025

REFERENCE NUMBER(S); CLASSIFICATION(S) & DETAIL(S)

12582643-1714 Pharmacy - Class E Business

Medical Gas Provider
Durable Medical Equipment Providers

DBA: ADVANTAGE HOME MEDICAL EQUIPMENT

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

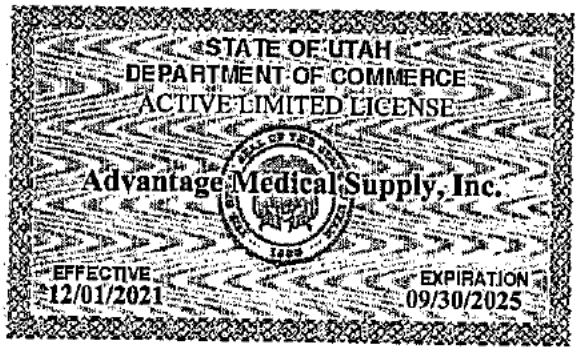
ADVANTAGE MEDICAL SUPPLY INC
[redacted] S HIGHWAY 89 APT[redacted]
KANAB UT 84741

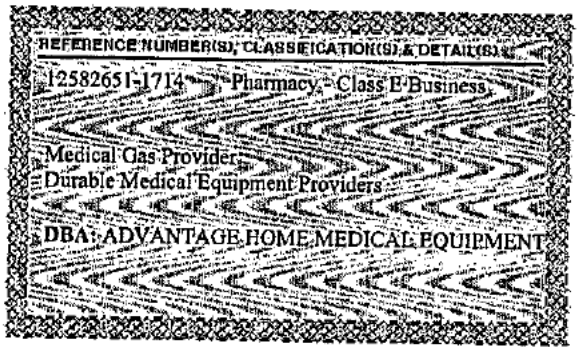
Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LIMITED LICENSE

EFFECTIVE DATE: 12/01/2021
EXPIRATION DATE: 09/30/2025
ISSUED TO: Advantage Medical Supply Inc
[redacted] S HIGHWAY 89 APT[redacted]
KANAB UT 84741

REFERENCE NUMBER(S); CLASSIFICATION(S) & DETAIL(S)
12582643-1714 Pharmacy - Class E Business
Medical Gas Provider
Durable Medical Equipment Providers
DBA: ADVANTAGE HOME MEDICAL EQUIPMENT



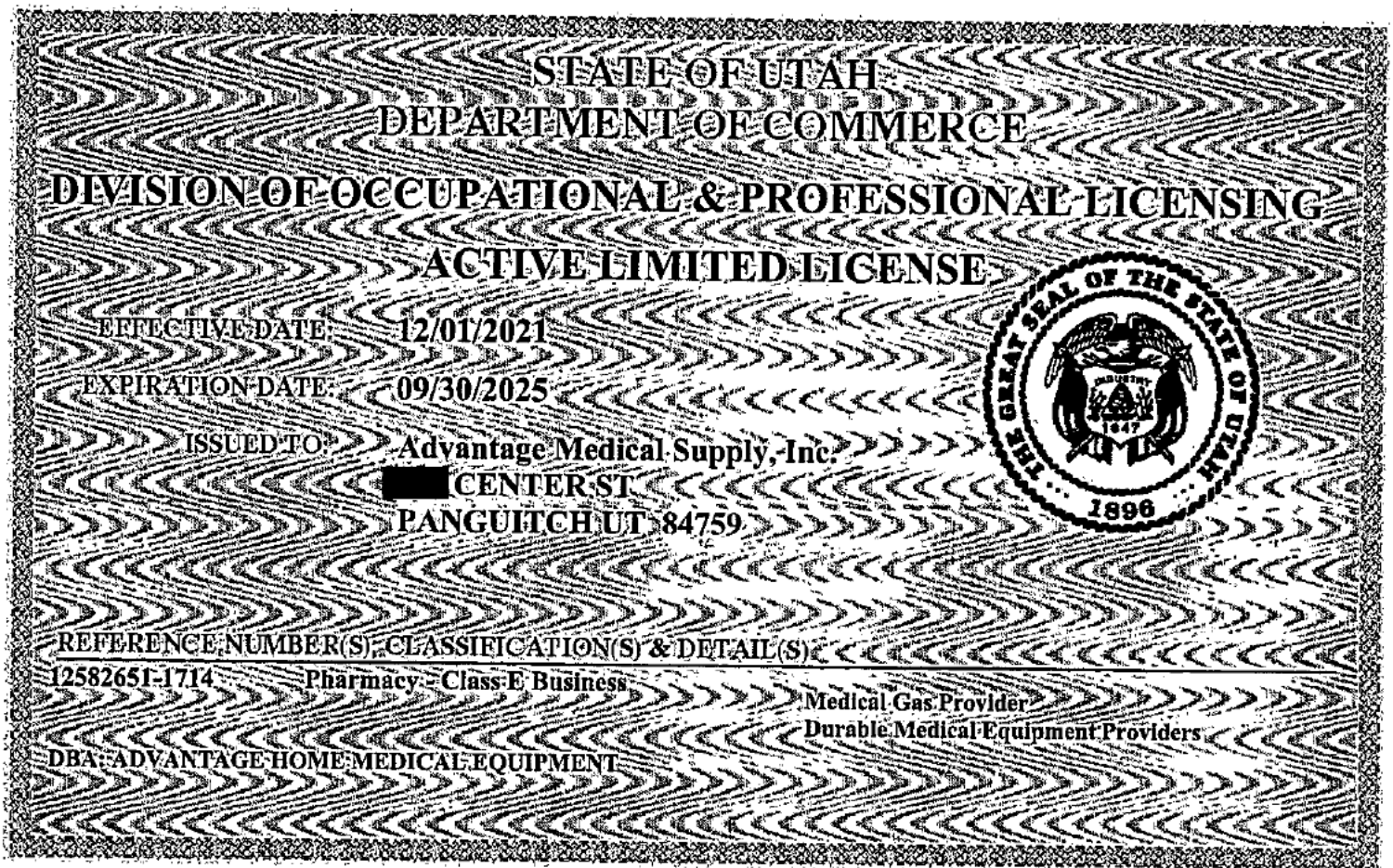


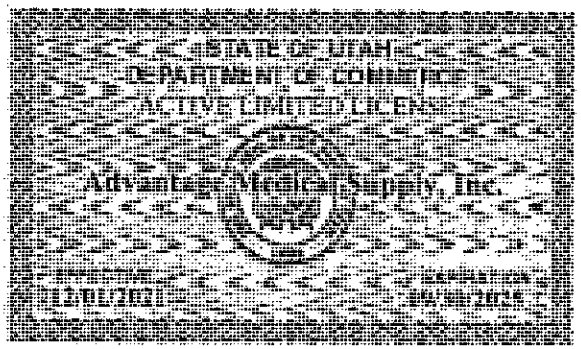
IMPORTANT LICENSURE REMINDERS:

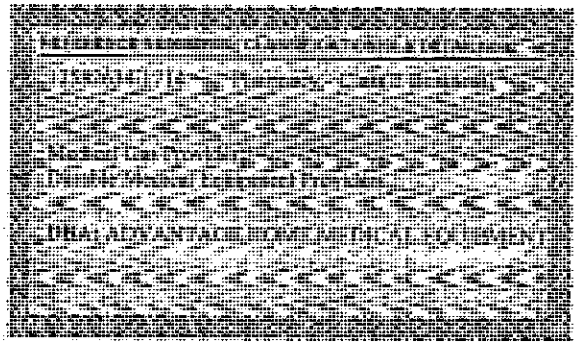
- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

ADVANTAGE MEDICAL SUPPLY, INC.
[redacted] CENTER ST
PANGUITCH UT 84759

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.





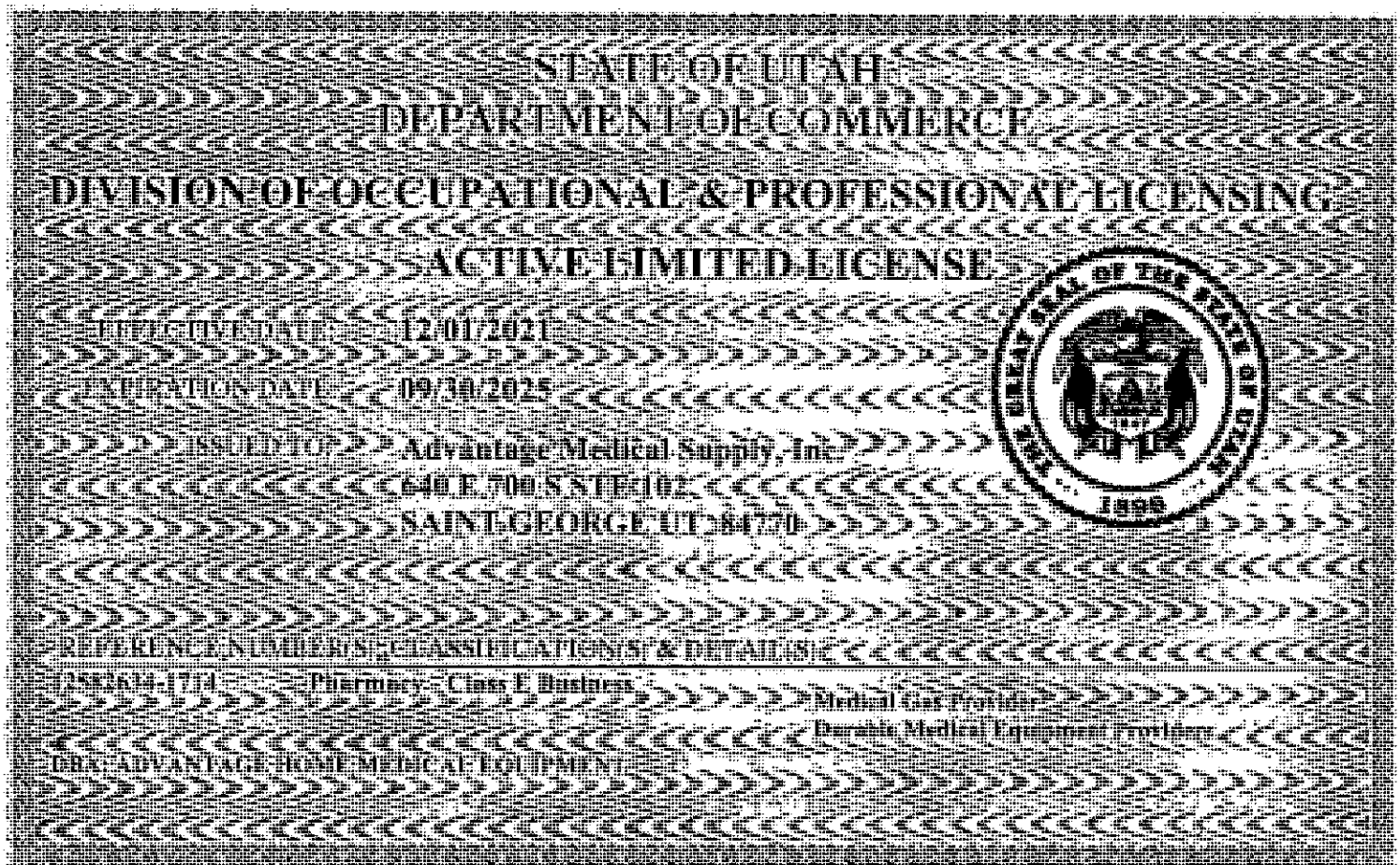


IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

ADVANTAGE MEDICAL SUPPLY, INC.
640 E 700 S STE 102
SAINT GEORGE UT 84770

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.



The Board of Certification / Accreditation, International

Owings Mills, Maryland, USA

Accredited Facility

Practice limited to DMEPOS supplier categories:

M01,DM02,DM03,R01,S02,DM09,DM10,R04,R06,R07,OR03,PD06,R08,M02,M03,R09,R10,
M04,DM20,DM26,S01,PD08,DM21,DM23,PD09,M05,M06,M06A,M07,M07A,M08,M08A,M
09,M09A,M10

The Board of Certification / Accreditation attests that the Facility named below complies with all requirements for facility accreditation.

Advantage Medical Supply, Inc.

590 Greenwood Dr

Brigham City, UT 84302-4736

This accreditation is awarded for meeting the professional standards of BOC, together with all the honors, rights, privileges and responsibilities in pursuit of our mission to assure patients, physicians, professional organizations, the public-at-large, and government agencies and representatives of the competence and professionalism of BOC-Accredited Facilities. In witness whereof, we have affixed the seal of the Board and subscribed our names in acknowledgement.

Matthew Gruskin, MBA, BOCO, BOCPD, Credentialing Director

Claudia Zacharias, MBA, CAE, President & CEO

S28847

Facility Number

July 2024

Accredited Through

Accredited Since: 2012

BOC is a CMS deemed accrediting organization.

This accreditation is the property of BOC — the certificate holder agrees to abide by the BOC / CMS standards.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 10/23/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Monica Taylor
Leavitt Group of Northern Utah 120 West Cache Valley Blvd Suite 110 Logan UT 84321	PHONE (A/C, No, Ext): (435)752-1351 FAX (A/C, No): (866)553-5245 E-MAIL ADDRESS: monica-taylor@leavitt.com
INSURED	**INSURER(S) AFFORDING COVERAGE** / **NAIC #**
Advantage Medical Supply 590 Greenwood Drive Brigham City UT 84302	INSURER A: Philadelphia Indemnity Insurance Compar 018058 INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** 2023-2024 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			PHPK2443329	7/23/2023	7/23/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 100,000 $ 5,000 $ 1,000,000 $ 3,000,000 $ 3,000,000
	AUTOMOBILE LIABILITY ANY AUTO ALL OWNED AUTOS HIRED AUTOS SCHEDULED AUTOS NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	UMBRELLA LIAB [ ] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Palmetto GBA, LLC
17 Technology Circle
Columbia, SC 29203

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Monica Taylor/MOTAYL

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Advantage Medical Supply, Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 350 Falcon Ridge Parkway Suite 103

City: Mesquite State: NV Zip: 89027

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 888-270-0202 Website: www.advantagehme.org

Licensing Company Email: support@advantagehme.org

Section 2: Personal Information

First: Shane Middle: Evan Last: Meacham

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]380 E

City: Smithfield State: UT Zip: 84335

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.179)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Utah State University			09/95-05/01	
Address	**City**		**State**	**Zip**
1435 Old Main Hill	Logan		UT	84322
Diploma/Degree obtained, if any				
Associates				

School Name			From - To (MM/YY – MM/YY)	
Dixie College			09/94-12/94	
Address	**City**		**State**	**Zip**
225 S University Ave	St. George		UT	84770
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Sky View High School			08/89-05/92	
Address	**City**		**State**	**Zip**
520 S 250 E	Smithfield		UT	84335
Diploma/Degree obtained, if any				
High School Diploma				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/05-Current	[redacted]380 E	Smithfield	UT	84335
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7- Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Advantage Medical Supply, Inc			04/15-Current	
Business Address		**City**	**State**	**Zip**
590 Greenwood Drive		Brigham City	UT	84302
Phone	**Title**			
(435) 734-0488	President			
Description of Duties				
Owner/President of full service DME company within Utah.				

Business Name			From - To (MM/YY – MM/YY)	
Cache Valley Oxygen			08/97-03/15	
Business Address		**City**	**State**	**Zip**
1395 N 400 E Ste A		Logan	UT	84341
Phone	**Title**			
435-752-2227	General Manager			
Description of Duties				
General manager for DME company in Northern Utah.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
04/24/2015	06/16	UT	Logan	Cache

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
150100173	First Judicial Justice Court

Reason/Charge
Service of complaint and notice to cease and desist

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Defendent	Lawsuit

Name of Business/Industry/Entity
Alpine Home Medical Equipment

Provide explanation below:

The plaintiff Alpine Home Medical Equipment came in and was in the process of purchasing the company I had worked for for 18 years Cache Valley Oxygen. After meeting with their management, my future with their company was very unsure and so we went out and purchased our own DME company Advantage Medical Supply in April 2015. When Alpine became aware of this they sued us for violating non-compete clauses which we had never had at any point and for in their words trade secret misappropriation along with a couple other false claims. Upon discovery, these were found to be all without merit and the lawsuit was dismissed and settled out of court in June 2016.

April 9, 2024

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shane Meacham

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

April 9, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of UTAH, ss. County of CACHE

I, SHANE MEACHAM, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/10/24

Date

Subscribed and Sworn to before me this 10th day of April.

Notary Public Signature

BENNETT ERICKSON
Notary Public
State Of Utah
My Commission Expires 04/28/2027
COMMISSION NO. 730853

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Advantage Medical Supply, Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 350 Falcon Ridge Parkway Suite 103

City Mesquite State NV Zip 89027

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 8882700202 Website www.advantagehme.org

Licensing Company Email support@advantagehme.org

Section 2: Personal Information

First Kory Middle Spencer Last Young

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Kanab State UT Zip 84741

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Alta High School		08/1981-05/1984	
Address	**City**	**State**	**Zip**
11000S 700 E	Sandy	UT	84070
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
University of Utah		09/1987-12/1988	
Address	**City**	**State**	**Zip**
201 Presidents Circl	SLC	UT	84112
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2106-Current	[redacted]Elbern's Road	Mt. Carmel	UT	84755
11/1995-02/2016	[redacted]1980 S	Clearfield	UT	84015

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Advantage Medical Supply, Inc			05/2015-Current	
Business Address		**City**	**State**	**Zip**
590 Greenwood Drive		Brigham City	UT	84302
Phone	**Title**			
4357340488	VP/Owner			
Description of Duties				
Managing owner. All daily managerial duties for multiple locations in UT and AZ.				

Business Name			From - To (MM/YY – MM/YY)	
Total Respiratory Care Inc.			06/1997 to 04/2015	
Business Address		**City**	**State**	**Zip**
1593 W 2350 S		Woods Cross	UT	84087
Phone	**Title**			
8012988831	General Manager/Minority Owner			
Description of Duties				
Managed location and responsible for sales and marketing.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4and5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/27/2015	06/16/2016	UT	Logan	Cache

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
150100173	First District Cache County, UT

Reason/Charge
Non-Compete issue

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Alpine Home Medical Plaintiff/Advantage Medical Defendant	Civil lawsuit

Name of Business/Industry/Entity
Advantage Medical Supply, Inc

Provide explanation below:

Kory Young as an owner of Total Respiratory Care that was acquired by Alpine Home Medical had been removed from any portion of the Purchase agreement pertaining to Non-Compete at his request. Kory Young joined Advantage Medical Supply once the acquisition was completed. Alpine Home Medical filed suit anyway and the suit was settled a few months later.

Original Signature (electronic, copies or stamps not accepted)

04/08/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kory Young

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/08/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Kane

I, Kory Young, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4-9-2024

Date

Subscribed and Sworn to before me this 9th day of April 2024

Notary Public Signature

NOTARY PUBLIC
Adina Jones
Commission No. 718784
My Commission Expires
06/14/2025
STATE OF UTAH

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Advantage Medical Supply, Inc MDEG License # (if applicable) _____

Physical Address 350 Falcon Ridge Parkway Suite 103

City Mesquite State NV Zip 89027

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 8882700202 Website www.advantagehme.org

Licensing Company Email support@advantagehme.org

Section 2: Personal Information

First Kolton Middle Alexander Last Young

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] River Road

City St. George State UT Zip 84790

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Utah Tech Universite		01/2014 to 05/2017	
Address	**City**	**State**	**Zip**
225 S University Ave	St George	UT	84770
Diploma/Degree obtained, if any			
Associates Degree			
School Name		**From - To (MM/YY – MM/YY)**	
Clearfield High School		08/2007 to 05/2010	
Address	**City**	**State**	**Zip**
931 S 1000 E	Clearfield	UT	84015
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2017 to 04/2023	[redacted]River Rd[redacted]	St. George	UT	84790
08/2015 to 11/2017	[redacted]5745 N	St. George	UT	84770
08/2013 to 08/2013	[redacted]Hope Street	St. George	UT	84770
08/2012 to 08/2013	[redacted]1040 N[redacted]	St. George	UT	84770
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Advantage Medical Supply, Inc			04/2015 to 04/2023
Business Address	**City**	**State**	**Zip**
640 E 700 S	St. George	UT	84770
Phone	**Title**		**Number of Employed Hours**
4356198003	DME Technician, Hospice Manager, Branch Manager		3000+
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/10/2024
Date

I, Kolton Young, **certify that as the MDEG Administrator for**

Advantage Medical Supply, Inc,

that I (initial that you have read and meet the following requirements):

1. KY Have a high school diploma or its equivalent;
2. KY Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KY Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KY Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kolton Young
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/09/2024
Date

Board Use Only	Date Received:

7B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located? ■ Nevada ☐ Out-of-State

[a]Is the business also a wholesaler? (NRS 639.016) ☐ Yes ■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: H-BLU MEDICAL SUPPLY LLC

MDEG Physical Address: 1101 W MOANA LANE SUITE 14

City: RENO State: NEVADA Zip: 89509

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (775) 357-9557 Website: H-BLUMEDICALSUPPLY.COM

Email: HBLUDME@GMAIL.COM

Name of MDEG Administrator (NAC 639.694): Barbi Lei Hamidi

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Canes,Crutches,Walkers,CGM,UV Wand,Braces
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: HASIBULLAH POPAL
	Telephone: (510)518-7032

Check the Days the Business will be Opened and provide the Hours of Operation

■ Mon	■ Tue	■ Wed	■ Thurs	Fri
Sat	Sun	Holidays		

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))

N/A

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: HASIBULLAH POPAL

Business Name: H-BLU MEDICAL SUPPLY LLC

Business Address: 1101 W MOANA LN SUITE 14

City: RENO State: NEVADA Zip: 89509

Telephone: (510) 518-7032 Email: HBLUDME@GMAIL.COM

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• "**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HASIBULLAH POPAL

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/02/2023

Date

Board Use Only	Date Received 1/10/24	Amount

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 10/12/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER

Jacoby Atako (6722336)
5325 S Fort Apache Rd. Ste F
Las Vegas NV 89148

CONTACT
NAME: Jacoby Atako
PHONE (A/C, NO, EXT): 702-476-8800
FAX (A/C, NO): 702-476-8802
E-MAIL ADDRESS: jatako@farmersagent.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A: Evanston Insurance Company	35378
INSURER B:	
INSURER C:	
INSURER D:	
INSURER E:	
INSURER F:	

INSURED

H-Blu Medical Supply LLC
1101 W Moana Ln #14
Reno NV 89509

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAME ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDTL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PROJECT [ ] LOC [ ] OTHER:	Y		3AA18282	10/05/2023	10/05/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea Occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 1,000,000 $ 100,000 $ 5,000 $ EXCLUDED $ 2,000,000 $ EXCLUDED $
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ $ $ $ $
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE [ ]	$ $ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/ EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [ ] If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					[ ] PER STATUTE [ ] OTHER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $ $

DESCRIPTION OF OPERATIONS/LOCATIONS/VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Jacoby Atako

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SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **H-BLU MEDICAL SUPPLY LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 09/28/2023, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/02/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202401024236097
You may verify this certificate online at http://www.nvsos.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler H-Blu Medical Supply LLC

Physical Address 1101 W. Moana Ln #14

City Reno State Nv Zip 89509

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 510-518-7032 Website H-blumedicalsupply.com

Licensing Company Email _____

Section 2: Personal Information

First Hasibullah Middle _____ Last Popal

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]egonia St

City Union City State Ca Zip 94587

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Applicant's initials H.P. H.P.

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
James Logan High School		2000-2004	
Address	City	State	Zip
1800 H Street	Union City	Ca	94587
Diploma/Degree obtained, if any	Diploma		
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2000-present	[redacted] Begonia St	Union City	Ca	94587
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials H.F

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
VACO		2021-PRESENT	
Business Address	**City**	**State**	**Zip**
2623 CAMINO RAMON	SAN RAMON	CA	94583
Phone	**Title**		
	MODERATOR		
Description of Duties			
Trust and Safety Content moderator			

Business Name		From - To (MM/YY – MM/YY)	
REGISTRAR OF VOTERS		2018-2021	
Business Address	**City**	**State**	**Zip**
	OAKLAND	CA	94607
Phone	**Title**		
	Admin Support		
Description of Duties			
Data management, organizing election equipment, material. worked on logistics. ran county elections			

Business Name		From - To (MM/YY – MM/YY)	
TAYYIBAAT MEAT & GRILL			
Business Address	**City**	**State**	**Zip**
10 S ABBOTT AVE	MILPITAS	CA	95037
Phone	**Title**		
Description of Duties			
ASSISTANT MANAGER			

Business Name		From - To (MM/YY – MM/YY)	
REALIANCE BAY FUNDING		2004-2010	
Business Address	**City**	**State**	**Zip**
N FIRST ST	SAN JOSE	CA	95134
Phone	**Title**		
	REALTOR/LOAN OFFICER		
Description of Duties			
Helped clients purchase/sell and refinance			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

H P

Applicant's initials H P

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG H-BLU MEDICAL SUPPLY LLC MDEG License # (if applicable) _____

Physical Address 1101 W. Moana Ln #14

City Reno State NV Zip 89509

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 775-357-9557 Website h-blumedicalsupply.com

Licensing Company Email _____

Section 2: Personal Information

First Barbi Middle lei Last Hamidi

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Castellina Way

City Manteca State CA Zip 95337

Telephone [redacted] Email _____

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
COMMONWEALTH HIGH SCHOOL		1997	
Address	**City**	**State**	**Zip**
PHILIPPINES			
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
INFORMATICS		2010	
Address	**City**	**State**	**Zip**
PHILIPPINES			
Diploma/Degree obtained, if any			
I.T BACHELOR DEGREE			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016-2021	[redacted] PAVILLION PKWY [redacted]	TRACY	CA	95304
2021-2024	[redacted] MOWRY AVE	FREMONT	CA	94538

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
RESHAPE MEDICAL EQUIPMENT LLC			10-19-2021-1-10-2024	
Business Address		**City**	**State**	**Zip**
1090 LA PLAYA DRIVE HAYWARD #210		HAYWARD	CA	94545
Phone	**Title**		**Number of Employed Hours**	
510-290-2229	MANAGEMENT			
Description of Duties				
MANAGING COMPLAINTS RETURNS HANDLING DAILY OPERATIONS , SHIPPING AND TRACKING, BILLING COORDINATOR				

Business Name			From - To (MM/YY – MM/YY)	
ZNB SOLUTIONS LLC			PRESENT	
Business Address		**City**	**State**	**Zip**
1090 LA PLAYA DRIVE #100		HAYWARD	CA	94545
Phone	**Title**		**Number of Employed Hours**	
510-4918671	MANAGER			
Description of Duties				
HR MANAGEMENT PAYROLL				

Business Name			From - To (MM/YY – MM/YY)	
S8 MEDICAL EQUIPMENT LLC			01/24-06/24	
Business Address		**City**	**State**	**Zip**
3155 Kearney St Suite # 170		FREMONT	CA	94538
Phone	**Title**		**Number of Employed Hours**	
(510)-573-1931	CONSULTANT MANAGER			
Description of Duties				
ENSURING THE OPERATION OF THE FACILITY COMPLIES WITH STATES AND LOCAL RULES AND REGULATIONS.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, BARBI LEI HAMIDI, **certify that as the MDEG Administrator for**

H-BLU MEDICAL SUPPLY, LLC,

that I (initial that you have read and meet the following requirements):

1. B.H Have a high school diploma or its equivalent;
2. B.H Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. B.H Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. B.H Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BARBI LEI HAMIDI
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

JULY 16 2023
Date

Board Use Only	Date Received:

7C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	■ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: MAXCARE MEDICAL EQUIPMENT LLC

MDEG Physical Address: 4483 W. RENO AVENUE

City: LAS VEGAS State: NV Zip: 89118

Mailing Address (if different from physical address): (SAME AS ABOVE)

City: _____ State: _____ Zip: _____

Telephone: 702-500-7778 Website: N/A

Email: MAXCAREMEDICALEQUIPMENT@GMAIL.COM

Name of MDEG Administrator (NAC 639.694): ALBERTO S. RAMOS

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: INCONTINENCE, WHEEL CHAIRS, WALKERS
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: N/A
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9-5	■ Tue: 9-5	■ Wed: 9-5	■ Thurs: 9-5	■ Fri: 9-5
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
N/A

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEVADA

Parent Company (if any): N/A

Corporation/Organization Name: MAXCARE MEDICAL EQUIPMENT LLC

Mailing Address: 4483 W. RENO AVENUE

City: LAS VEGAS State: NV Zip: 89118

Telephone: 702-500-7778 Email: MAXCAREMEDICALEQUIPMENT@GMAIL.COM

Contact Person Name: FRANK HO

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

VANESSA OW

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

07-05-24

Date

Board Use Only	Date Received: 7/9/24	Amount: $500-ck 6262

FRANCISCO V. AGUILAR
Secretary of State

DEPUTY BAKKEDAHL
Deputy Secretary for
Commercial Recordings

STATE OF NEVADA

OFFICE OF THE
SECRETARY OF STATE

Commercial Recordings Division
401 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

05/10/2024

Work Order Item Number:	W20240510001795 - 3677223
Filing Number:	20244054484
Filing Type:	Articles of Organization
Filing Date/Time:	05/10/2024 17:12:11 PM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: E40544852024-0

Entity Name: Maxcare Medical Equipment LLC

Entity Status: Active

Expiration Date: None

Non-Commercial Registered Agent
Vanessa Ow
4483 W. Reno Avenue, Las Vegas, NV 89118, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Maxcare Medical Equipment LLC** did, on 05/10/2024, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/10/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202405104641609
You may verify this certificate
online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Maxcare Medical Equipment LLC

Nevada Business Identification # NV20243116653
Expiration Date: 05/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/10/2024.

Certificate Number: B202405104641610
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE Managing Member:

Name	Country	Address	City	State	Zip/Postal Code
Vanessa Ow	USA	4483 W. Reno Avenue	Las Vegas	NV	89118

CORPORATION, INDICATE THE Managing Member:

Name	Country	Address	City	State	Zip/Postal Code
Yan Du	USA	4483 W. Reno Avenue	Las Vegas	NV	89118

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X Vanessa Ow
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Managing Member
Title

05/10/2024
Date

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 07/02/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	**CONTACT NAME:** Jessica Flores
AssuredPartners of Nevada LLC	**PHONE (A/C, No, Ext):** (702) 638-0022 **FAX (A/C, No):** (702) 638-0050
375 E Warm Springs Rd Ste 201	**E-MAIL ADDRESS:** jessica.flores@assuredpartners.com
Las Vegas NV 89119	**INSURER(S) AFFORDING COVERAGE** / **NAIC #** **INSURER A :** Continental Casualty Company / 20443
INSURED	**INSURER B :**
Maxcare Medical Equipment LLC	**INSURER C :**
4483 West Reno	**INSURER D :**
	INSURER E :
Las Vegas NV 89118	**INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** 2024-2025 Master **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			7038895318	07/02/2024	07/02/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ 2,000,000
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N / A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

For Informational Purposes Only.

CERTIFICATE HOLDER

Evidence of insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Kathryn Goosen

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Maxcare Medical Equipment LLC
4483 W. Reno Avenue
Las Vegas, NV 89118

List of all Officers and Directors;

Managing Members:	Yan Du (Marketing and Accounting) Vanessa Ow (Purchasing and Logistic)
Administrator and Chief of Operation:	Alberto Ramos

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Maxcare Medical Equipment LLC
Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) N/A
Physical Address 4483 W. Reno Ave
City Las Vegas State NV Zip 89118
Mailing Address (if different from physical address) _____
City _____ State _____ Zip _____
Telephone 702-500-7778 Website _____
Licensing Company Email maxcaremedicalequipment@gmail.com

Section 2: Personal Information

First Vanessa Middle Wynii Last Ow
Alias(es, nicknames, name changes, etc.) N/A
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address [redacted] Camelback Peak Ct
City Las Vegas State NV Zip 89148
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
College of Southern Nevada		01/16 - 05/16	
Address	**City**	**State**	**Zip**
6375 Charleston Blvd	Las Vegas	NV	89146
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada Las Vegas		08/13 - 08/14	
Address	**City**	**State**	**Zip**
4505 S Maryland Pkwy	LAS Vegas	NV	89154
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Durango High School		08/09 - 06/13	
Address	**City**	**State**	**Zip**
7100 W Dewey Dr	Las Vegas	NV	89113
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/09 - 07/24	[redacted] Camelback Peak Ct	Las Vegas	NV	89148
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Southwest Airlines			08/23 - 07/24
Business Address	**City**	**State**	**Zip**
2702 Love Field Dr	Dallas	TX	75235
Phone	**Title**		
1800-435-9792	Flight Attendant		

Description of Duties
Keep passengers safe, ensuring that everyone follows security regulations and that the flight deck is secure.

Business Name			From - To (MM/YY – MM/YY)
MGM Resorts and Casino			03/16 - 02/21
Business Address	**City**	**State**	**Zip**
3790 Las Vegas Blvd	Las Vegas	NV	89109
Phone	**Title**		
(702)740-6969	Fountain Worker		

Description of Duties
Barista a New York New York's Starbucks as well as money handling

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vanessa Ow
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07-05-24
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Vanessa Ow, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7.5.24
Date

State of Nevada
County of Clark
Subscribed and Sworn to before me this 5 day of July 2024

Notary Public Signature

BECKY GONZALES
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 11-4473-1
MY APPT. EXPIRES APRIL 10, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site MAXCARE MEDICAL EQUIPMENT LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) N/A

Physical Address 4483 W. RENO AVENUE

City LAS VEGAS State NV Zip 89118

Mailing Address (if different from physical address) (SAME AS ABOVE)

City _____ State _____ Zip _____

Telephone 702-500-7778 Website N/A

Licensing Company Email MAXCARE MEDICAL EQUIPMENT@GMAIL.COM

Section 2: Personal Information

First YAN Middle _____ Last DU

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] DESERT LIME CT.

City LAS VEGAS State NV Zip 89148

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
CITY COLLEGE OF SAN FRANCISCO			01/2006 – 06/2008	
Address		City	State	Zip
50 FRIDA KAHLO WAY		SAN FRANCISCO	CA	94112
Diploma/Degree obtained, if any				
NONE				

School Name			From - To (MM/YY – MM/YY)	
HARBIN NORMAL UNIVERSITY			08/1997 – 07/2001	
Address		City	State	Zip
VH63+CX3, SHIDA RD. HULAN DISTRICT		HARBIN/CHINA	HJ	150025
Diploma/Degree obtained, if any				
BA DEGREE				

School Name			From - To (MM/YY – MM/YY)	
HARBIN 122 HIGH SCHOOL			09/1993 – 06/1997	
Address		City	State	Zip
XUSHENG STREET, XIANGFANG DISTRICT		HARBIN/CHINA	HJ	150036
Diploma/Degree obtained, if any				
DIPLOMA				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2024 – 07/2024	[redacted] DESERT LIME CT.	LAS VEGAS	NV	89148
From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2014 – 02/2024	[redacted] HONORS COURSE DR	LAS VEGAS	NV	89148
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
MAXSHARE MEDICAL EQUIPMENT LLC			05/2024 – PRESENT
Business Address	**City**	**State**	**Zip**
4463 W. RENO AVE.	LAS VEGAS	NV	89118
Phone	**Title**		
702-500-7778	MEMBER		
Description of Duties			
MANAGEMENT.			

Business Name			From - To (MM/YY – MM/YY)
CITIBANK			06/2008 – 09/2010
Business Address	**City**	**State**	**Zip**
429 PASEO GRANDE	SAN LORENZO	CA	94580
Phone	**Title**		
510-931-5222	CLERK		
Description of Duties			
CUSTOMER SERVICES.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/3/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

YAN DU
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/3/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Yan Du, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/3/2024
Date

Subscribed and Sworn to before me this 3 day of July.

Madison Pescado
Notary Public Signature

MADISON PESCADO
Notary Public - State of Nevada
Appointment No. 23-0218-01
My Appointment Expires 9-3-2027
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG MAXCARE MEDICAL EQUIPMENT LLC MDEG License # (if applicable) N/A

Physical Address 4483 W. RENO AVENUE

City LAS VEGAS State NV Zip 89118

Mailing Address (if different from physical address) (SAME AS ABOVE)

City _____ State _____ Zip _____

Telephone 702-500-7778 Website N/A

Licensing Company Email MAXCAREMEDICALEQUIPMENT@GMAIL.COM

Section 2: Personal Information

First ALBERTO Middle SOLOMON Last RAMOS

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] STEPHANIE STREET [redacted]

City HENDERSON State NV Zip 89014

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
MAPUA INSTITUTE OF TECHNOLOGY		01/1970-06/1974	
Address	**City**	**State**	**Zip**
658 MURALLA STREET	MANILA/PHILIPPINES	MANILA	1002
Diploma/Degree obtained, if any			
DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2023-07/2024	[redacted] STEPHANIE STREET [redacted]	HENDERSON	NV	89014
05/2012-02/2023	[redacted] CORVALLIS CT.	HENDERSON	NV	89074

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
FAMILY CARE MEDICAL SUPPLY			08/1989-08/1995	
Business Address		**City**	**State**	**Zip**
94-889 WAIPAHU STREET SUITE 103		WAIPAHU	HI	96797
Phone	**Title**		**Number of Employed Hours**	
808-861-4018	PARTNER/MANAGER		13,440	
Description of Duties				
MANAGEMENT, SALES/MARKETING, DELIVERY, INSTALLATION, SCHEDULING, BILLING, PURCHASING, ACCOUNTING				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07/02/2024
Date

I, ALBERTO RAMOS, **certify that as the MDEG Administrator for**

MAXCARE MEDICAL EQUIPMENT LLC,

that I (initial that you have read and meet the following requirements):

1. I Have a high school diploma or its equivalent;
2. I Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. I Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. I Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ALBERTO RAMOS
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/02/2024
Date

Board Use Only	Date Received: 7/9/24

8

8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ■ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number: ASC02399 ~~3981-ASC-22~~	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
■ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *		■ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Alta Rose Surgery Center

Physical Address: 501 Rose St, Suite 110

City: Las Vegas State: NV Zip: 89106

Mailing Address (if different from physical address): Same

City: Same State: Same Zip: Same

Telephone: 702-386-9906 Fax: 702-386-9910

Contact Email: sbroecker@compeye-care.com Website N/A

Nevada Business License # NV20041169336

Employed/Contracted Pharmacist Name: Mary Grear, Rph NV Pharmacist License #: 10687

Medical Director Name: Ksenia Stafeeva, MD

Days of Operation

☐ Monday	☐ Tuesday	☐ Wednesday	■ Thursday	■ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 5: Partnership

Partnership Name: Comprehensive Eyecare Partners ASC LV Holdings, LLC

Mailing Address: 2850 West Horizon, Ridge Parkway, Suite 120

City: Henderson State: NV Zip: 89052

Telephone: 702-857-6510 Email: sbroecker@compeye-care.com

Contact Person Name: Stephanie Broecker

Please check type of partnership (NAC 639.214) ☐ General ■ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ■ No

Section 6: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Mary Grear, RPh NV Pharmacist License #: 10687

As the employed/contracted pharmacist, for (ASC/RC Name): Alta Rose Surgery Center :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
4/24/2002	May 2002	NV	Las Vegas	Clark

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
02-036-RPH-S	NV State Board of Pharmacy

Reason/Charge
Complaint concerning records of PRN, Inc.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Mary Grear	

Name of Business/Industry/Entity
PRN, Inc.

Provide explanation below:

A complaint was made concerning grants made by the Board of Pharmacy to PRN, Inc. under the care of Mary Grear, Executive Director. The Board of Pharmacy sent notice of a request for hearing to the wrong mailing address even though the correct address was on file at the Board Office. This resulted in my not being aware that I needed to appear until after the Board Meeting. I subsequently prepared the requested documents and submitted them to the Board Auditors who found no discrepencies in the funds granted by the Board of Pharmacy to PRN and the expense record under my administration. A rehearing was held and the case was closed finding all monies were accounted for the PRN, Inc. gronts.

Mary Grear, RPh
Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

4/1/2024
Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KEVIN CAHILL

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4-5-2024

Date

Board Use Only	Date Received: 4/11/24	Amount: $500 CC

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AMSURG HOLDINGS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF APRIL, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "AMSURG HOLDINGS, LLC" WAS FORMED ON THE FOURTEENTH DAY OF JULY, A.D. 2014.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





5567812 8300

SR# 20241267267

Authentication: 203160737

Date: 04-02-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

ALTA-ROSE SURGERY CENTER, LLC

Nevada Business Identification # NV20041169336
Expiration Date: 07/31/2024

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 06/08/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202306083713987
You may verify this certificate online at http://www.nvsos.gov

BUSINESS LICENSE

CITY OF LAS VEGAS | LAS VEGAS, NEVADA

IN ACCORDANCE WITH THE PROVISIONS OF THE LAS VEGAS MUNICIPAL CODE, AS AMENDED, LICENSE IS HEREBY GRANTED TO OPERATE THE BUSINESS REFERENCED BELOW. FAILURE TO MAINTAIN AN ACTIVE STATE LICENSE OR SNHD HEALTH PERMIT, IF REQUIRED, RENDERS THIS LICENSE INVALID.

LICENSE #: G65-07180
TYPE: P55-AMBULATORY SURG CTR
BUSINESS LOCATION: 501 ROSE ST 110
ISSUED TO: ALTA ROSE-SURGERY CENTER LLC
75 ENTERPRISE, SUITE 200
ALISO VIEJO, CA 92656

RENEWAL: 10/1/2023
EXPIRATION DATE: 10/1/2024

Darcy Adelbai-Hurd
Business Licensing Manager

POST IN A CONSPICUOUS PLACE

FM-0152-08-22
Form 167

recycled paper

Please fold or cut along perforated line

This space intentionally left blank

Delaware

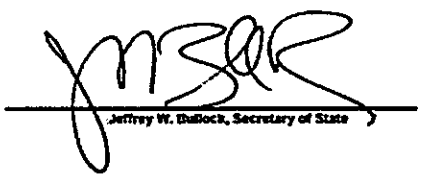
The First State

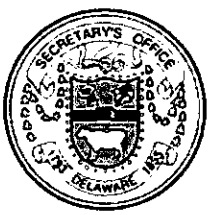
I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED ARE TRUE AND CORRECT COPIES OF ALL DOCUMENTS ON FILE OF "COMPREHENSIVE EYECARE HOLDINGS, LLC" AS RECEIVED AND FILED IN THIS OFFICE.

THE FOLLOWING DOCUMENTS HAVE BEEN CERTIFIED:

CERTIFICATE OF FORMATION, FILED THE TWENTY-SIXTH DAY OF JANUARY, A.D. 2018, AT 1:35 O`CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID LIMITED LIABILITY COMPANY, "COMPREHENSIVE EYECARE HOLDINGS, LLC".





6716114 8100H
SR# 20180657474

Authentication: 202076489
Date: 02-01-18

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF DELAWARE

CERTIFICATE OF FORMATION

OF

COMPREHENSIVE EYECARE HOLDINGS, LLC

This Certificate of Formation of COMPREHENSIVE EYECARE HOLDINGS, LLC is being executed and filed by Jon Freedman as an authorized person to form a limited liability company under the Delaware Limited Liability Company Act, 6 Delaware Code, Section 18.

FIRST: The name of the limited liability company is COMPREHENSIVE EYECARE HOLDINGS, LLC.

SECOND: The address of the registered office of limited liability company in the State of Delaware is 251 Little Falls Drive, City of Wilmington, County of New Castle, State of Delaware 19808. The Corporation Service Company is the limited liability company's registered agent at that address.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Formation to be signed this 26th day of January 2018.

AUTHORIZED PERSON:

Jon Freedman

Jon Freedman

SMRH:485190122.4

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:35 PM 01/26/2018
FILED 01:35 PM 01/26/2018
SR 20180526103 - File Number 6728387

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Alta-Rose Surgery Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) N/A

Physical Address 501 Rose St, Suite 110

City Las Vegas State NV Zip 89106

Mailing Address (if different from physical address) NA

City _____ State _____ Zip _____

Telephone 702-386-9906 Website NA

Licensing Company Email Current Ownership: Bryan.Yatabe@nvisioncenters.com

Section 2: Personal Information

First KEVIN [redacted] Middle REED Last CAHILL

Alias(es, nicknames, name changes, etc.) —

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] W 1st AVE

City GOLDEN State CO Zip 80401

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? NA		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
RICE UNIVERSITY		08/02-05/06	
Address	**City**	**State**	**Zip**
6100 MAIN ST	HOUSTON	TX	77005
Diploma/Degree obtained, if any: B.S.			

School Name		From - To (MM/YY – MM/YY)	
THOMAS JEFFERSON HIGH SCHOOL		09/98-06/02	
Address	**City**	**State**	**Zip**
6560 BRADDOCK RD	ALEXANDRIA	VA	22312
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/02-present	[redacted] W 1st AVE	GOLDEN	CO	80401
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
COMPREHENSIVE EYECARE PARTNERS			02/24 - Present	
Business Address		**City**	**State**	**Zip**
2850 W HORIZON RIDGE PKWY		HENDERSON	NV	89052
Phone	**Title**			
702-915-7000	COO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
DISPATCH HEALTH			08/23 - 02/24	
Business Address		**City**	**State**	**Zip**
3825 LAFAYETTE ST		DENVER	CO	80205
Phone	**Title**			
303-500-1518	SVP, OPERATIONS			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
DAVITA INC			01/14 - 08/23	
Business Address		**City**	**State**	**Zip**
2000 16TH ST		DENVER	CO	80202
Phone	**Title**			
800-244-0680	VICE PRESIDENT			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? NA		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KEVIN, CAHILL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4-9-2024

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, Kevin Cahill, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4-9-2024

Date

Subscribed and Sworn to before me this 8th day of April 2024

Notary Public Signature

STEPHANIE BROECKER
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 14-14758-1
My Appt. Expires September 16, 2026

(Seal)

DocuSign Envelope ID: 4465FF4A-E170-4053-8C00-399BC88E18AC

Comprehensive EyeCare
Partners

April 8, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy., Suite 206
Reno, NV 89521

Dear Licensing Committee:

I, Kevin Cahill, COO of Comprehensive Eyecare Partners, LLC, authorize the following individuals to represent the Change of Ownership for Alta Rose Surgery Center on my behalf.

REPRESENTATIVES:
Stephanie Broecker, VP of ASC Operations, Comprehensive Eye Care Partners
Mary Grear RPh, Consulting Pharmacist

Should you have any questions, you may contact me at kcahill@comp-eyecare.com.

Thank you,

DocuSigned by:
Kevin Cahill
BF04A38015E34CE...

Kevin Cahill
Chief Operating Officer

2850 W Horizon Ridge Pkwy Ste 300 | Henderson, NV 89052
Phone: 702-915-7000 | Fax: 702-210-6110

9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☒ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #:		☐ Other:
	PH_____		

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: DIAMOND SPECIALTY PHARMACY

Physical Address: 4825 S. FORT APACHE ROAD SUITE A

City: LAS VEGAS State: NV Zip: 89147

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 775-762-2359 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: [redacted]

Website: www.diamondpharmacynv.com

Nevada Business License # (if applicable) NV20243129090

Supervising/Managing Pharmacist Name (NRS 639.220): EARL MATTHEW PEREGRINO

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23299

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: EARL MATTHEW PEREGRINO	NV Pharmacist Registration #: 23299
Name: ALBA HERNANDEZ GAONA	NV Pharmacist Registration #: 20407
Name: SAUL UMAÑA JR.	NV Pharmacist Registration #: 23942
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A.	Credentials: n/a.	%: n/a.
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: EARLMATTHEW PEREGRINO

Business Name: DIAMOND SPECIALTY PHARMACY LLC

Business Address: 4825 S FT. APACHE RD SUITE A.

City: LAS VEGAS State: NV Zip: 89147.

Telephone: (775) 762-2359 Email: diamondpharmacy23@gmail.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PHARMACIST IN CHARGE (title) for DIAMOND SPECIALTY PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

EARL MATTHEW PEREGRINO

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

07|04|2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, EARLMATHEW PEREGRINO hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PHARMACIST IN CHARGE (title) for DIAMOND SPECIALTY PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 11th day of July, 2024

Jennifer I. Nevarez Mijares
Notary Public

JENNIFER I NEVAREZ MIJARES
Notary Public
State of Nevada
Appt. No. 23-1072-01
My Appt. Expires May 17, 2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: EARL MATHEW PEREGRINO Pharmacist Registration #: 23299

Pharmacy Name: DIAMOND SPECIALTY PHARMACY

Initial each statement below to indicate you have read and agree with the following:

mp. I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

mp. I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

mp. I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

mp. I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

mp. I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

07/04/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

EARL MATTHEW A. PEREGRINO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

07/04/2024.

Date

Board Use Only	Date Received: 7/15/24	Amount: 500-CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler DIAMOND SPECIALTY PHARMACY LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) n/a.

Physical Address 4825 S. FORT APACHE ROAD SUITE A

City LAS VEGAS State NV Zip 89147

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (775) 762-2359 Website www.diamondpharmacynv.com

Licensing Company Email diamondpharmacy23@gmail.com

Section 2: Personal Information

First EARL MATTHEW Middle ADRIANO Last PEREGRINO

Alias(es, nicknames, name changes, etc.) MATT

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] CROWN PALMS AVE.

City LAS VEGAS State NV Zip 89139

Telephone [redacted] mail [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ROSEMAN UNIVERSITY OF HEALTH SCIENCE		08/19 - 05/22	
Address: 11 SUNSET WAY	City: HENDERSON	State: NV	Zip: 89014
Diploma/Degree obtained, if any: DOCTOR OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF NEVADA LAS VEGAS.		08/16 - 05/19.	
Address: 4505 S. MARYLAND PKWY	City: LAS VEGAS	State: N	Zip: 89154.
Diploma/Degree obtained, if any: N/G.			

School Name		From - To (MM/YY – MM/YY)	
TRUCKEE MEADOWS COMMUNITY COLLEGE		08/11 - 08/15	
Address: 7000 DANDINI BLVD	City: RENO	State: NV	Zip: 89512
Diploma/Degree obtained, if any:			

School Name		From - To (MM/YY – MM/YY)	
RENO HIGH SCHOOL		08/07 - 05/11	
Address: 395 BOOTH STREET	City: RENO	State: NV	Zip: 89509.
Diploma/Degree obtained, if any:			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any:			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/22 - NOW	[redacted] CROWN PALMS AVE	LAS VEGAS.	NV	89139.
12/18 - 01/22	[redacted] TAWNY MILL STREET	LAS VEGAS.	NV	89148
12/16 - 12/18	[redacted] BIRD CHERRY STREET	LAS VEGAS	NV	89148
01/14 - 12/16.	[redacted] LEADERSHIP PKWAY	RENO	NV	89503.
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: ASP CARES.			From - To (MM/YY – MM/YY): 11/22 - NOW
Business Address: 501 S. RANCHO DRIVE G-46	City: LAS VEGAS	State: NV	Zip: 89106.
Phone: 702-912-4844.	Title: Registered Pharmacist.		
Description of Duties: Pharmacist.			

Business Name: PAIN SPECIALTY PHARMACY/HOSPITAL.			From - To (MM/YY – MM/YY): 11/23 - NOW
Business Address: 235 W. 6TH STREET	City: RENO	State: NV	Zip: 89503
Phone: (775) - 473-2078.	Title: Registered Pharmacist		
Description of Duties: Pharmacist			

Business Name: CVS PHARMACY			From - To (MM/YY – MM/YY): 02/16 - 5/22.
Business Address: 3270 S. BUFFALO DRIVE	City: LAS VEGAS	State: NV	Zip: 89117
Phone: (702) 256-1205.	Title: Pharmacy Technician.		
Description of Duties: Pharmacy technician			

Business Name: CVS PHARMACY.			From - To (MM/YY – MM/YY): 08/15 - 12/16.
Business Address: 1695 ROBB DRIVE	City: RENO	State: NV	Zip: 89523.
Phone: 775-746-1600	Title: Pharmacy Technician		
Description of Duties: Pharmacy technician / inventory specialist.			

Business Name: Renown HEALTH			From - To (MM/YY – MM/YY): 04/14 - 12/15.
Business Address: 1155 Mill STREET	City: RENO	State: NV	Zip: 89502.
Phone: 775-982-4100	Title: Compounding Technician.		
Description of Duties: Compounding Pharmacy Technician			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Walgreens Pharmacy.			05/12 - 4/14.	
Business Address 750 N. VIRGINIA STREET		City RENO	State NV	Zip 89501
Phone 775-337-8703	Title SENIOR / LEAD PHARMACY TECHNICIAN.			
Description of Duties LEAD PHARMACY TECHNICIAN.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

EARUMATTHEW PEREGRINO

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/04/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, EARUMATTHEW PEREGRINO, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/11/2024.

Date

Subscribed and Sworn to before me this 11th day of July.

Notary Public Signature

JENNIFER I NEVAREZ MIJARES
Notary Public
State of Nevada
Appt. No. 23-1072-01
My Appt. Expires May 17, 2027

(Seal)

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Diamond Specialty Pharmacy LLC** did, on 05/29/2024, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/29/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202405294683527
You may verify this certificate
online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

NEVADA STATE BUSINESS LICENSE

Diamond Specialty Pharmacy LLC

Nevada Business Identification # NV20243129090
Expiration Date: 05/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/29/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202405294683528
You may verify this certificate online at https://www.nvsilverflume.gov/home

9B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: To be obtained
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: District Pharmacy

Physical Address: 1807 West Charleston Boulevard, Suite 110

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): 2505 Anthem Village Drive, Suite E, #460

City: Henderson State: NV Zip: 89052

Telephone: (408) 338-8513 Toll Free # (NAC 639.708, NRS 639.23286): N / A

Fax: To be obtained Contact Email: thedistrictpharmacy@gmail.com

Website: N / A

Nevada Business License # (if applicable) NV20243070654

Supervising/Managing Pharmacist Name (NRS 639.220): Janice Gange

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 16744

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Janice Gange	NV Pharmacist Registration #: 16744
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N / A	Credentials: N / A	%: N / A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 69SC of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N / A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): N / A

Corporation/Organization Name: District Pharmacy Corporation

Mailing Address: 2505 Anthem Village Drive, Suite E #460

City: Henderson State: NV Zip: 89052

Telephone: 4083388513 Email: thedistrictpharmacy@gmail.com

Contact Person Name: George Gange

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N / A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N / A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for District Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

George Gange

Print Name of Authorized Person

George Gange

Original signature of Authorized Person (copies or stamps not accepted)

26-March-2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, George Gange hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for District Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

George Gange
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 26th day of March, 2024

Justine Belen
Notary Public

Notary Public - State Of Nevada
COUNTY OF CLARK
JUSTINE BELEN
My Appointment Expires
August 1, 2027
No. 23-1182-01

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Janice Gange Pharmacist Registration #: 16744

Pharmacy Name: District Pharmacy

Initial each statement below to indicate you have read and agree with the following:

JG I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

JG I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

JG I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

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JG I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
N / A	N / A	N / A	N / A

Criminal Action:	State:	Date:	Case #:	County:	Court:
N / A	N / A	N / A	N / A	N / A	N / A

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

March, 20th 2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

George Gange

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

George Gange

Original signature of Authorized Person (copies or stamps not accepted)

26-March-2024

Date

Board Use Only	Date Received: 3/28/24	Amount: $500-cc

The SilverFlume Business Portal will be unavailable Tuesday, April 16th from 7:00 PM until midnight (12:00AM) for scheduled maintenance. We apologize for any inconvenience this may cause.

SilverFlume
NEVADA'S BUSINESS PORTAL

CBR Detail Report

Business Name: District Pharmacy Corporation

v1 - APPROVED - 04/03/2024 14:02:02

Current Version

Prior Versions

NV Business ID	NV20243070654
Entity Type	Domestic Corporation (78)
Entity Status	Active
State Business License Expiration Date	Mar 31, 2025
Last Updated By	[redacted]
Last Updated Date	2024-04-03 13:50:30.0

Company Officers

Title	Name	Address
Secretary	George Gange	[redacted] Anthem Village Dr Henderson NV
President	Janice Gange	[redacted] Anthem Village Dr Henderson NV
Treasurer	George Gange	[redacted] Anthem Village Dr Henderson NV
President	George Gange	[redacted] Anthem Village Dr Henderson NV
Director	Janice Gange	[redacted] Anthem Village Dr Henderson NV
Director	George Gange	[redacted] Anthem Village Dr Henderson NV

Compliance Information

State Business License:	Completed on 03/11/2024
B&I Workers' Compensation eAffirmation of Compliance (D-25)	Completed on 04/03/2024
Nevada Labor Laws eAffirmation of Compliance:	Completed on 04/03/2024
OSHA/Safety Consultation and Training (SCATS)	Completed on 04/03/2024
NV Dept of Taxation eClearance Receipt:	Completed on 04/03/2024
Department of Motor Vehicles:	Not Complete

Declaration

George Gange on Apr 3, 2024

Export Information

Do you have a Nevada Location or conduct sales and services in Nevada? **Yes**
Do you sell goods and services outside the State of Nevada? **No**
Would you be interested to learn more about opportunities to expand your business outside Nevada? **Yes**
Federal Employer Identification Number: 99 1980518

Business Information

Primary NAICS Code:	446110 - Pharmacies and Drug Stores
Applicable NAICS Codes:	446110 - Pharmacies and Drug Stores
Business Description:	Provide healthcare and sales of prescription and non-prescription drugs to the general public.

Owner Information

Name	Title	Percent Owned	Address	Contact Number	Last Updated By	Last Updated Date
George Gange	President	50	2505 ANTHEM VILLAGE DRIVE SUITE E #460, HENDERSON, NV 89052	US408-504-3193	[redacted]	2024-04-03 13:53:29.0
Janice Gange	President	50	2505 ANTHEM VILLAGE DRIVE SUITE E #460, HENDERSON, NV 89052	US408-504-3783	[redacted]	2024-04-03 13:53:29.0

Location Information

Primary Location	
Fictitious Firm Name/DBA:	
Applicable NAICS Codes:	446110 - Pharmacies and Drug Stores
Business Description:	Provide healthcare services and retail sales of prescription and non-prescription drugs to the general public.
Date Opened in NV:	Apr 4, 2024
Total # of Employees:	2
Total Part-Time Employees:	0
Total Full-Time Employees:	2
Physical Address:	1807 WEST CHARLESTON BOULEVARD SUITE 110, LAS VEGAS, NV 89102
Jurisdiction:	
Zoning:	
Assessor Parcel Number:	
Property Ownership:	
County:	Clark County
Mailing Address:	2505 ANTHEM VILLAGE DRIVE SUITE E #460, HENDERSON, NV 89052
Phone:	(408) 338-8513
Fax:	
Last Updated By:	[redacted]
Last Updated Date:	2024-04-03 13:53:29.0

Sales & Services (Non-Bricks & Mortar)

Fictitious Firm Name / DBA	County	City
None Entered	Clark County	City of Las Vegas

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC CORPORATION (78) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **District Pharmacy Corporation** did, on 03/11/2024, file in this office the original Articles of Incorporation-For-Profit that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 03/11/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202403114454969
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

District Pharmacy Corporation

Nevada Business Identification # NV20243070654
Expiration Date: 03/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 03/11/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202403114454970
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State

DEPUTY BAKKEDAHL
Deputy Secretary for Commercial Recordings

STATE OF NEVADA

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings & Notary Division
401 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Cheyenne Moseley
[redacted]N Brand Blvd.
Glendale, CA 91203, USA

Work Order #: W2024031102618
March 11, 2024
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 760226

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Articles of Incorporation-For-Profit • 1,500@0.01 Common = $15.00 • # Of No Par Values Shares 0 • Authorized Value $15.00	Fees	20243906342	3/11/2024 6:44:35 PM	InternalReview	1	$75.00	$75.00
Initial List	Fees	20243906344	3/11/2024 6:44:36 PM	InternalReview	1	$150.00	$150.00
Initial List	Business License Fee	20243906344	3/11/2024 6:44:36 PM	InternalReview	1	$500.00	$500.00
Total							$725.00

Payments

Type	Description	Payment Status	Amount
Trust Account	750957	Success	$725.00
Total			$725.00

Credit Balance: $0.00

Cheyenne Moseley
[redacted]N Brand Blvd.
Glendale, CA 91203, USA

STATE OF NEVADA

FRANCISCO V. AGUILAR
Secretary of State

DEPUTY BAKKEDAHL
Deputy Secretary for Commercial Recordings

OFFICE OF THE SECRETARY OF STATE

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Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Articles of Incorporation-For-Profit • 1,500@0.01 Common = $15.00 • # Of No Par Values Shares 0 • Authorized Value $15.00	Fees	20243906342	3/11/2024 6:44:35 PM	InternalReview	1	$75.00	$75.00
Initial List	Fees	20243906344	3/11/2024 6:44:36 PM	InternalReview	1	$150.00	$150.00
Initial List	Business License Fee	20243906344	3/11/2024 6:44:36 PM	InternalReview	1	$500.00	$500.00
Total							$725.00

Payments

Type	Description	Payment Status	Amount
Trust Account	750957	Success	$725.00
Total			$725.00

Credit Balance: $0.00

Cheyenne Moseley
[redacted]N Brand Blvd.
Glendale, CA 91203, USA

FRANCISCO V. AGUILAR
Secretary of State

DEPUTY BAKKEDAHL
Deputy Secretary for
Commercial Recordings

STATE OF NEVADA

OFFICE OF THE
SECRETARY OF STATE

Commercial Recordings Division
401 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

03/11/2024

Work Order Item Number:	W2024031102618 - 3530469
Filing Number:	20243906342
Filing Type:	Articles of Incorporation-For-Profit
Filing Date/Time:	03/11/2024 18:44:35 PM
Filing Page(s):	3

Indexed Entity Information:

Entity ID: E39063432024-1

Entity Name: District Pharmacy Corporation

Entity Status: Active

Expiration Date: None

Commercial Registered Agent
UNITED STATES CORPORATION AGENTS, INC.
6605 Grand Montecito Pkwy, Suite 100, Las Vegas, NV 89149, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

FRANCISCO V. AGUILAR
Secretary of State

STATE OF NEVADA

FRANCISCO V. AGUILAR
Secretary of State

DEPUTY BAKKEDAHL
Deputy Secretary for Commercial Recordings

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings Division
401 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

03/11/2024

Work Order Item Number:	W2024031102618 - 3530470
Filing Number:	20243906344
Filing Type:	Initial List
Filing Date/Time:	03/11/2024 18:44:36 PM
Filing Page(s):	3

Indexed Entity Information:

Entity ID: E39063432024-1

Entity Name: District Pharmacy Corporation

Entity Status: Active

Expiration Date: None

Commercial Registered Agent
UNITED STATES CORPORATION AGENTS, INC.
6605 Grand Montecito Pkwy, Suite 100, Las Vegas, NV 89149, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

FRANCISCO V. AGUILAR
Secretary of State

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Filed in the Office of	Business Number
FVAguilar	E39063432024-1
	Filing Number
Secretary of State	20243906342
State Of Nevada	Filed On
	03/11/2024 18:44:35 PM
	Number of Pages
	3

Formation - Profit Corporation

☑ NRS 78 - Articles of Incorporation Profit Corporation ☐ NRS 80 - Foreign Corporation ☐ NRS 89 - Articles of Incorporation Professional Corporation

☐ 78A Formation - Close Corporation

(Name of closed corporation MUST appear in the below heading)

Articles of Formation of _____ **a close corporation (NRS 78A)**

TYPE OR PRINT - USE DARK INK ONLY - DO NOT HIGH LIGHT

1. Name of Entity: (If foreign, name in home jurisdiction)

District Pharmacy Corporation

2. Registered Agent for Service of Process: (Check only one box)

☑ Commercial Registered Agent (name only below) ☐ Noncommercial Registered Agent (name and address below) ☐ Office or position with Entity (title and address below)

UNITED STATES CORPORATION AGENTS, INC.
Name of Registered Agent **OR** Title of Office or Position with Entity

6605 Grand Montecito Pkwy, Suite 100 — Las Vegas — Nevada 89149
Street Address — City — Zip Code

Mailing Address (If different from street address) — City — Nevada — Zip Code

2a. Certificate of Acceptance of Appointment of Registered Agent:

I hereby accept appointment as Registered Agent for the above named Entity. If the registered agent is unable to sign the Articles of Incorporation, submit a separate signed Registered Agent Acceptance form.

X Cheyenne Moseley, United States Corporation Agents, Inc. — 03/11/2024
Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity — Date

3. Governing Board: (NRS 78A, close corporation only, check one box; if yes, complete article 4 below)

This corporation is a close corporation operating with a board of directors ☐ Yes **OR** ☑ No

4. Names and Addresses of the Board of Directors/ Trustees or Stockholders

(NRS 78: Board of Directors/ Trustees is required.

NRS 78a: Required if the Close Corporation is governed by a board of directors.

NRS 89: Required to have the Original stockholders and directors. A certificate from the regulatory board must be submitted showing that each individual is licensed at the time of filing. See instructions)

1) George Wong Gange
Name
2505 Anthem Village Dr Ste E #460 — Henderson — NV — 89052
Address — City — State — Zip Code

2) Janice Soriano Gange
Name
2505 Anthem Village Dr Ste E #460 — Henderson — NV — 89052
Address — City — State — Zip Code

5. Jurisdiction of Incorporation: (NRS 80 only)

5a. Jurisdiction of incorporation:

5b. I declare this entity is in good standing in the jurisdiction of its incorporation. ☐

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Formation - profit Corporation

Continued, Page 2

6. Benefit Corporation:
(For NRS 78, NRS 78A, and NRS 89, optional. See instructions.)

By selecting "Yes" you are indicating that the corporation is organized as a benefit corporation pursuant to NRS Chapter 78B with a purpose of creating a general or specific public benefit. The purpose for which the benefit corporation is created must be disclosed in the below purpose field.

Yes ☐

7. Purpose/Profession to be practiced:
(Required for NRS 80, NRS 89 and any entity selecting Benefit Corporation. See instructions.)

8. Authorized Shares:
(Number of shares corporation is authorized to issue)

Please indicate the break down of all corporate shares and the par value.

Number of Authorized shares with Par value: 0 — Par value: $ 0

Number of common shares with Par value: 1500.0 — Par value: $ 0.01

Number of preferred shares with Par value: 0 — Par value: $ 0

Number of shares with no par value: **0**

Foreign Corporations, NRS 80 only:

☐ This is a corporation is a unlimited stock corporation

☐ This is a corporation is a non-stock corporation.

If more than one class or series of stock is authorized, please attach the information on an additional sheet of paper.

9. Name and Signature of: Officer making the statement or Authorized Signer for NRS 80.
Name, Address and Signature of the Incorporator for NRS 78, 78A, and 89. NRS 89 - Each Organizer/ Incorporator must be a licensed professional.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

Name	Country		
George Wong Gange	United States		
Address	**City**	**State**	**Zip/Postal Code**
2505 Anthem Village Dr, Ste E #460	Henderson	NV	89052

X George Wong Gange (attach additional page if necessary)

Name	Country		
Janice Soriano Gange	United States		
Address	**City**	**State**	**Zip/Postal Code**
2505 Anthem Village Dr, Ste E #460	Henderson	NV	89052

X Janice Soriano Gange (attach additional page if necessary)

AN INITIAL LIST OF OFFICERS MUST ACCOMPANY THIS FILING

Please include any required or optional information in space below:
(attach additional page(s) if necessary)

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

District Pharmacy Corporation

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☑ Corporation

☐ This corporation is publicly traded, the Central Index Key number is:

Filed in the Office of	Business Number
FVAguilar	**E39063432024-1**
	Filing Number
	20243906344
Secretary of State	Filed On
State Of Nevada	**03/11/2024 18:44:36 PM**
	Number of Pages
	3

☐ Nonprofit Corporation (see nonprofit sections below)

☐ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)

☐ Business Trust

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

☐ 001 - Governmental Entity

☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming and exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80:Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required

☐ Yes - the *Charitable Solicitation Registration Statement* is required.

☐ The Organization claims exemption pursuant to NRS 82A 210 - the *Exemption From Charitable Solicitation Registration Statement* is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE President:

Name	Country
George Wong Gange	USA

Address	City	State	Zip/Postal Code
2505 Anthem Village Dr Ste E #460	Henderson	NV	89052

CORPORATION, INDICATE THE Secretary:

Name	Country
George Wong Gange	USA

Address	City	State	Zip/Postal Code
2505 Anthem Village Dr Ste E #460	Henderson	NV	89052

CORPORATION, INDICATE THE Treasurer:

Name	Country
George Wong Gange	USA

Address	City	State	Zip/Postal Code
2505 Anthem Village Dr Ste E #460	Henderson	NV	89052

CORPORATION, INDICATE THE President:

Name	Country
Janice Soriano Gange	USA

Address	City	State	Zip/Postal Code
2505 Anthem Village Dr Ste E #460	Henderson	NV	89052

CORPORATION, INDICATE THE Director:

Name	Country
George Wong Gange	USA

Address	City	State	Zip/Postal Code
2505 Anthem Village Dr Ste E #460	Henderson	NV	89052

CORPORATION, INDICATE THE Director:

Name	Country
Janice Soriano Gange	USA

Address	City	State	Zip/Postal Code
2505 Anthem Village Dr Ste E #460	Henderson	NV	89052

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X George Wong Gange

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

President — Title

03/11/2024 — Date

X George Wong Gange

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Secretary — Title

03/11/2024 — Date

X George Wong Gange

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Treasurer — Title

03/11/2024 — Date

X Janice Soriano Gange

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

President — Title

03/11/2024 — Date

X George Wong Gange

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Director — Title

03/11/2024 — Date

X Janice Soriano Gange

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Director — Title

03/11/2024 — Date

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: District Pharmacy

Pharmacy/Wholesaler License # (if applicable): To be obtained

Physical Address: 1807 West Charleston Boulevard, Suite 110

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): 2505 Anthem Village Drive, Suite E #460

City: Henderson State: NV Zip: 89052

Telephone: (408) 338-8513 Website: N / A

Licensing Company Email: thedistrictpharmacy@gmail.com

Section 2: Personal Information

First: Janice Middle: Soriano Last: Gange

Alias(es, nicknames, name changes, etc.): N / A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 2505 Anthem Village Drive, Suite E #460

City: Henderson State: NV Zip: 89052

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Southern Nevada, College of Pharmacy			09/02 - 05/05	
Address	City	State	Zip	
11 Sunset Way	Henderson	NV	89014	
Diploma/Degree obtained, if any				
Doctor of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
San Jose State University			08/97 - 05/02	
Address	City	State	Zip	
One Washington Square	San Jose	CA	95192	
Diploma/Degree obtained, if any				
Bachelor of Science in Molecular Biology, Minor in Chemistry				
School Name			From - To (MM/YY – MM/YY)	
Overfelt High School			09/95 - 06/97	
Address	City	State	Zip	
1835 Cunningham Ave	San Jose	CA	95122	
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Notre Dame High School			09/93 - 06/95	
Address	City	State	Zip	
596 S. 2nd Street	San Jose	CA	95112	
Diploma/Degree obtained, if any				
Transferred to Overfelt High School				
School Name			From - To (MM/YY – MM/YY	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/23 - Present	[redacted]Penn Cross Court	Henderson	NV	89052
03/06 - 04/23	[redacted]Piedmont Road	San Jose	CA	95132
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Santa Clara Valley Medical Center, Hospital, and Clinics			09/16 - 03/20	
Business Address		**City**	**State**	**Zip**
2221 Enborg Lane		Santa Clara	CA	95128
Phone	**Title**		**Number of Employed Hours**	
(408) 885-6220	Pharmacist, On-Call / Per Diem		684.9	

Description of Duties
Responded to, processed, and optimized prescription refill requests; Improved management of chronic conditions, by assuring and allowing patients with access to a continuous supply of maintenance medications and diabetic supplies.

Business Name			From - To (MM/YY – MM/YY)	
Safeway			03/14 - 02/18	
Business Address		**City**	**State**	**Zip**
5918 Stoneridge Mall Road		Pleasanton	CA	94588
Phone	**Title**		**Number of Employed Hours**	
(800) 723-3929	Pharmacist, On-Call / Per Diem		1,514.35	

Description of Duties
Supervised pharmacy interns, technicians, and clerks; Entered, reviewed, filled, and dispensed prescription orders accurately and efficiently; Assisted technicians with inventory control and performed related record keeping duties.

Business Name			From - To (MM/YY – MM/YY)	
Target			07/05 - 07/13	
Business Address		**City**	**State**	**Zip**
3155 Silver Creek Rd, San Jose, CA 95121		San Jose	CA	95121
Phone	**Title**		**Number of Employed Hours**	
(408) 238-7800	Executive Pharmacist		8,192	

Description of Duties
Managed day to day operations of the Pharmacy team; Entered, reviewed, filled, and dispensed prescription orders accurately and efficiently; Assisted technicians with inventory control and performed related record keeping duties.

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			04/04 - 07/05	
Business Address		**City**	**State**	**Zip**
4340 S Valley View Blvd		Las Vegas	NV	89109
Phone	**Title**		**Number of Employed Hours**	
(702) 889-8274	Graduate Intern Pharmacist		500	

Description of Duties
Counseled patients and/or caregivers on the appropriate use of prescription medications; Documented patient-specific information demonstrated through entries in patient profiles, prescriptions, medication orders, consult, and progress notes.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

March 26th, 2024
Date

I, Janice Gange, **certify that as the designated representative for**

District Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JG I am at least 21 years of age;
3. JG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Janice Gange

Print Name (First, Last)

Janice Gange

Original Signature (electronic, copies or stamps not accepted)

March 26th, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Janice Gange

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

March 26th, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Janice Gange, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/26/2024

Date

Subscribed and Sworn to before me this 26th day of March 2024

Notary Public Signature

Notary Public - State Of Nevada
COUNTY OF CLARK
JUSTINE BELEN
My Appointment Expires
August 1, 2027
No. 23-1182-01

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: District Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1807 West Charleston Boulevard, Suite 110

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): 2505 Anthem Village Drive, Suite E #460

City: Henderson State: NV Zip: 89052

Telephone: (408) 338-8513 Website: N / A

Licensing Company Email: thedistrictpharmacy@gmail.com

Section 2: Personal Information

First: Janice Middle: Soriano Last: Gange

Alias(es, nicknames, name changes, etc.): N / A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address: 2505 Anthem Village Drive, Suite E #460

City: Henderson State: NV Zip: 89052

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern Nevada, College of Pharmacy		09/02 - 05/05	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
San Jose State University		08/97 - 05/02	
Address	**City**	**State**	**Zip**
One Washington Square	San Jose	CA	95192
Diploma/Degree obtained, if any			
Bachelor of Science in Molecular Biology, Minor in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Overfelt High School			
Address	**City**	**State**	**Zip**
1835 Cunningham Ave	San Jose	CA	95122
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Notre Dame High School		09/93 - 06/95	
Address	**City**	**State**	**Zip**
596 S. 2nd Street	San Jose	CA	95112
Diploma/Degree obtained, if any			
Transferred to Overfelt High School			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/23 - Present	[redacted]Penn Cross Court	Henderson	NV	89052
03/06 - 04/23	[redacted]Piedmont Road	San Jose	CA	95132
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
District Pharmacy Corporation			03/24 - Present	
Business Address	**City**		**State**	**Zip**
2505 Anthem Village Drive, Suite E #460	Henderson		NV	89052
Phone	**Title**			
(408) 338-8513	President, Director, Shareholder, Owner			
Description of Duties				
Strategic planning; Optimizing medication management system; Ensuring quality outcomes; Drug utilization management; Regulatory and accreditation compliance; Supply Chain Management; Managing the pharmacy work force.				

Business Name			From - To (MM/YY – MM/YY)	
Santa Clara Valley Medical Center, Hospital, and Clinics			09/16 - 03/20	
Business Address	**City**		**State**	**Zip**
2221 Enborg Lane	Santa Clara		CA	95128
Phone	**Title**			
(408) 885-6220	Pharmacist, On-Call / Per Diem			
Description of Duties				
Responded to, processed, and optimized prescription refill requests; Improved management of chronic conditions, by assuring and allowing patients with access to a continuous supply of maintenance medications and diabetic supplies.				

Business Name			From - To (MM/YY – MM/YY)	
Safeway			03/14 - 02/18	
Business Address	**City**		**State**	**Zip**
5918 Stoneridge Mall Road	Pleasanton		CA	94588
Phone	**Title**			
(800) 723-3929	Pharmacist, On-Call / Per Diem			
Description of Duties				
Supervised pharmacy interns, technicians, and clerks; Entered, reviewed, filled, and dispensed prescription orders accurately and efficiently; Assisted technicians with inventory control and performed related record keeping duties.				

Business Name			From - To (MM/YY – MM/YY)	
Target			07/05 - 07/13	
Business Address	**City**		**State**	**Zip**
3155 Silver Creek Rd	San Jose		CA	95121
Phone	**Title**			
(408) 238-7800	Executive Pharmacist			
Description of Duties				
Managed day to day operations of the Pharmacy team; Entered, reviewed, filled, and dispensed prescription orders accurately and efficiently; Assisted technicians with inventory control and performed related record keeping duties.				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			04/04 - 07/05	
Business Address	**City**		**State**	**Zip**
4340 S Valley View Blvd	Las Vegas		NV	89109
Phone	**Title**			
(702) 889-8274	Graduate Intern Pharmacist			
Description of Duties				
Counseled patients and/or caregivers on the appropriate use of prescription medications; Documented patient-specific information demonstrated through entries in patient profiles, prescriptions, medication orders, consult, and progress notes.				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

March 26th, 2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Janice Gange

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

March 26th, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Janice Gange, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/26/2024

Date

Subscribed and Sworn to before me this 26th day of March 2024

Notary Public Signature

Notary Public - State Of Nevada
COUNTY OF CLARK
JUSTINE BELEN
My Appointment Expires
August 1, 2027
No. 23-1182-01

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: District Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1807 West Charleston Boulevard, Suite 110

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): 2505 Anthem Village Drive, Suite E #460

City: Henderson State: NV Zip: 89052

Telephone: (408) 338-8513 Website: N / A

Licensing Company Email: thedistrictpharmacy@gmail.com

Section 2: Personal Information

First: George Middle: Wong Last: Gange

Alias(es, nicknames, name changes, etc.): N / A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 2505 Anthem Village Drive, Suite E #460

City: Henderson State: NV Zip: 89052

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
San Jose State University	08/96 - 05/01		
Address	**City**	**State**	**Zip**
One Washington Square	San Jose	CA	95192
Diploma/Degree obtained, if any			
B.S. Business Administration with a Concentration in Management Information Systems			

School Name	From - To (MM/YY – MM/YY)		
Piedmont Hills High School	09/92 - 06/96		
Address	**City**	**State**	**Zip**
1377 Piedmont Rd	San Jose	CA	95132
Diploma/Degree obtained, if any			
High School Diploma			

School Name	From - To (MM/YY – MM/YY)		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY)		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/23 - Present	[redacted] Penn Cross Court	Henderson	NV	89052
03/06 - 04/23	[redacted] Piedmont Road	San Jose	CA	95132

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
District Pharmacy Corporation			03/24 - Present
Business Address	**City**	**State**	**Zip**
2505 Anthem Village Drive, Suite E #460	Henderson	NV	89052
Phone	**Title**		
(408) 338-8513	President, Director, Shareholder, Owner		

Description of Duties
Manage change; Make staff effective; Review business performance on a monthly and quarterly basis to ensure the organization is performing as desired; Direct marketing; Organize information and knowledge. Support the P.I.C.

Business Name			From - To (MM/YY – MM/YY)
LinkedIn Corporation			03/10 - 12/23
Business Address	**City**	**State**	**Zip**
1000 W. Maude Ave.	Sunnyvale	CA	94085
Phone	**Title**		
(650) 687-3600	Systems Engineer		

Description of Duties
Designed, architected, tested, implemented, and maintained information security identity and access management systems; Created architectural and authentication flow diagrams, policies, and procedures; Trained support personnel.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

George Gouge
Original Signature (electronic, copies or stamps not accepted)

26-March-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

George Gange

Print Name (First, Last)

George Gange — 26-March-2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, George Gange, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

George Gange — 26-March-2024

Original Signature — **Date**

Subscribed and Sworn to before me this 26th day of March 2024

Justine Belen

Notary Public Signature

Notary Public - State Of Nevada
COUNTY OF CLARK
JUSTINE BELEN
My Appointment Expires
August 1, 2027
No. 23-1182-01

(Seal)

9C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: STAYWELL PHARMACY

Physical Address: 3950 E. SUNSET RD. SUITE 111

City: LAS VEGAS State: NV Zip: 89120

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 2132651152 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: PENDING Contact Email: erwin.cuenca@yahoo.com

Website: PENDING

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): ROCHELLE ROZALDO MITCHELL

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 17047

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: ROCHELLE ROZALDO MITCHELL	NV Pharmacist Registration #: 17047
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: MCLV INNOVATION ENTERPRISES INC

Mailing Address: [redacted]

City: HENDERSON State: NV Zip: 89011

Telephone: 2132651152 Email: [redacted]

Contact Person Name: ERWIN CUENCA

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility – MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the OWNER (title) for STAYWELL PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

ERWIN CUENCA

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/9/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, ERWIN CUENCA hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OWNER (title) for STAYWELL PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 09th day of APRIL, 2024

Notary Public

Notary Public - State Of Nevada
COUNTY OF CLARK
MADISON BENNETT
My Appointment Expires
August 28, 2027
No. 23-3406-01

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: ROCHELLE ROZALDO MITCHELL Pharmacist Registration #: 17047

Pharmacy Name: STAYWELL PHARMACY

Initial each statement below to indicate you have read and agree with the following:

RRM I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

RRM I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

RRM I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

RRM I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

RRM I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

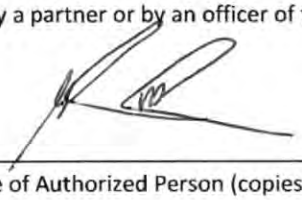
Rochelle R. Rozaldo Mitchell
Original signature of Managing Pharmacist (copies or stamps not accepted)

4/9/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ERWIN CUENCA

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

4/9/24

Date

Board Use Only	Date Received: 4/11/24	Amount: $500-CC

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **MCLV INNOVATION ENTERPRISES Inc**, as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/29/2022, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/17/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202405174658071
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application

☑ ANNUAL ☐ AMENDED (check one)

List of Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

MCLV INNOVATION ENTERPRISES Inc
NAME OF ENTITY

NV20222410037
Entity or Nevada Business Identification Number (NVID)

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☑ Corporation
☐ This corporation is publicly traded, the Central Index Key number is:

☐ Nonprofit Corporation (see nonprofit sections below)

☐ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership

☐ Business Trust

☐ Corporation Sole

Filed in the Office of	Business Number
FVAguilar	E22066372022-2
	Filing Number
	20244032737
Secretary of State	Filed On
State Of Nevada	05/01/2024 16:14:07 PM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.
☐ 001 - Governmental Entity
☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming an exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80:Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required
☐ Yes - the "Charitable Solicitation Registration Statement" is required.
☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE President:

Name	Country
ERWIN CUENCA	USA

Address	City	State	Zip/Postal Code
[redacted]	Henderson	NV	89011

CORPORATION, INDICATE THE Treasurer:

Name	Country
MIA JOY CUENCA	USA

Address	City	State	Zip/Postal Code
[redacted]	Henderson	NV	89011

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X ERWIN CUENCA
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

President
Title

05/01/2024
Date

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site STAYWELL PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 3950 E. SUNSET RD. SUITE 111

City LAS VEGAS State NV Zip 89120

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 2132651152 Website _____

Licensing Company Email erwin.cuenca@yahoo.com

Section 2: Personal Information

First ERWIN Middle E Last CUENCA

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] MONROE HILL PL

City HENDERSON State NV Zip 89011

Telephon[redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
MARIANAS HIGH SCHOOL		08/83-05/89	
Address	**City**	**State**	**Zip**
PO BOX 500207	SAIPAN	MP	96950
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/23 - PRESENT	[redacted]MONROE HILL PL	HENDERSON	NV	89011
04/18-09/23	[redacted]CADENCE VIEW WAY	HENDERSON	NV	89011
05/07-04/18	[redacted]ONGSHOT DR	LAS VEGAS	NV	89122

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
STATE MEDICAL EQUIPMENT			07/20-PRESENT
Business Address	**City**	**State**	**Zip**
3950 E. SUNSET RD. SUITE 112	LAS VEGAS	NV	89120
Phone	**Title**		
702-538-9555	INVENTORY ASSOCIATES		

Description of Duties

keeps track of the goods and supplies in a store or warehouse and manages orders to facilitate sales or production. Other duties include signing off on shipments, counting the number of available products and placing orders for more inventory according to demand

Business Name			From - To (MM/YY – MM/YY)
HILTON GRAND VACATION ON THE LAS VEGAS STRIP			02/07-07/20
Business Address	**City**	**State**	**Zip**
2650 SOUTH LAS VEGAS BLVD.	LAS VEGAS	NV	89109
Phone	**Title**		
702-765-8300	FRONT DESK AGENT		

Description of Duties

Checking guests in and out of ther room and provide general information about the property. Assist guests both in person and online to reserve their room. And accommodate any special needs or requests .

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ERWIN CUENCA
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/9/24
Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, ERWIN CUENCA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/9/24
Date

Subscribed and Sworn to before me this 09th day of APRIL 2024

Notary Public Signature

Notary Public - State Of Nevada
COUNTY OF CLARK
MADISON BENNETT
My Appointment Expires
No. 23-3406-01 August 28, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler STAYWELL PHARMACY

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 3950 E. SUNSET RD. SUITE 111

City LAS VEGAS State NV Zip 89120

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 213-265-1152 Website _____

Licensing Company Email erwin.cuenca@yahoo.com

Section 2: Personal Information

First Rochelle Middle Remolona Last Rozaldo-Mitchell

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Dire Wolf Ave.

City North Las Vegas State NV Zip 89084

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of the East Ramon Magsaysay Memorial Medical Center		6/1993 – 4/1997	
Address	City	State	Zip
64 Aurora Blvd	Quezon City	Philippines	1113
Diploma/Degree obtained, if any			
Doctor of Medicine			

School Name		From - To (MM/YY – MM/YY)	
University of Santo Tomas		6/1988 – 3/1992	
Address	City	State	Zip
España Blvd, Sampaloc	Manila	Philippines	
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Santo Tomas		6/1985 – 3/1988	
Address	City	State	Zip
España Blvd, Sampaloc	Manila	Philippines	
Diploma/Degree obtained, if any			
High school			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2019 - present	[redacted] Dire Wolf Ave	North Las Vegas	NV	89084
6/2013 - 9/2019	[redacted] Salt Basin St	North Las Vegas	NV	89084
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)
VA Pharmacy		8/2018 – present
Business Address	**City** / **State** / **Zip**	
6900 N. Pecos Rd	North Las Vegas / NV / 89086	
Phone	**Title**	**Number of Employed Hours**
702-791-9000	Outpatient Pharmacist	10,880 Hours

Description of Duties
Perform all duties of a clinical outpatient pharmacist. Review all medication orders for appropriateness, drug selection, dosage, route of administration & the amount, prior to dispensing

Business Name		From - To (MM/YY – MM/YY)
Walgreens Pharmacy		11/2006 – 8/2015
Business Address	**City** / **State** / **Zip**	
6825 N. Durango Dr.	Las Vegas / NV / 89149	
Phone	**Title**	**Number of Employed Hours**
702-260-8242	Staff Pharmacist	23,040 Hours

Description of Duties
Accurately fill prescriptions; Review and identify drug interactions, potentially dangerous side effects, appropriate dosage requirements and calculations. Attend to both medical professionals and patients.

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City** / **State** / **Zip**	
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City** / **State** / **Zip**	
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City** / **State** / **Zip**	
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Rochelle R. Rozaldo-Mitchell, **certify that as the designated representative for**

STAYWELL PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RRM I am at least 21 years of age;
3. RRM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RRM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RRM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RRM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RRM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Rochelle R. Rozaldo-Mitchell

Print Name (First, Last)

Rochelle R. Rozaldo-Mitchell

Original Signature (electronic, copies or stamps not accepted)

4/9/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rochelle R. Rozaldo-Mitchell

Print Name (First, Last)

Rochelle R. Rozaldo-Mitchell

Original Signature (electronic, copies or stamps not accepted)

4/9/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Rochelle Remolona Rozaldo-Mitchell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Rochelle R. Rozaldo-Mitchell

Original Signature

4/9/2024

Date

Subscribed and Sworn to before me this 9th day of April, 2024

Notary Public Signature Domonique Dorantes

DOMONIQUE DORANTES
Notary Public, State of Nevada
Appointment No. 23-8408-01
My Appt. Expires Mar 5, 2027

(Seal)

9D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ■ Ownership Change* ☐ Location Change * ☐ Service Modification* ☑ Name Change* (If only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH IB02706	☐ Retail/Community ■ Hospital (# beds 114) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ■ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	■ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Thrive Behavioral Hospital Pharmacy

Physical Address: 5900 W Rochelle Ave

City: Las Vegas State: NV Zip: 89103

Mailing Address (if different from physical address): _____

City: Las Vegas State: NV Zip: 89103

Telephone: 702-486-6492 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 725-677-8144 Contact Email: tkosut@apcpharm.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Timothy Edward Kosut

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 14802

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Timothy Edward Kosut	NV Pharmacist Registration #: 14802
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	✓	
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 3, Ques. 1 and 3

Indirect owners Elliott Cohen and Michael Cohen have disclosed arrests in 2006 and 2008 for drug possession on their Personal History Applications. They have each attempted unsuccessfully to obtain copies of records related to these cases, both from their attorneys and from the courts, due to the records having been expunged many years ago and to the remoteness of the arrests themselves. The Cohens assure the BOP that the arrests were related to young adult antics, and are not indicative of any current substance abuse issues or representative of their character and integrity.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): none

Corporation/Organization Name: Thrive Behavioral Hospital, LLC

Mailing Address: 5900 W. Rochelle Ave

City: Las Vegas State: NV Zip: 89103

Telephone: 702-522-7922 Email: smirato@desertwindshospital.com

Contact Person Name: Shelly Mirato, CEO

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☑ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the president (title) for Thrive Behavioral Hospital Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Nissim A Bejar

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

3/13/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Timothy Edward Kosut hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Director (title) for Thrive Behavioral Hospital Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Timothy Edward Kosut
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of March, 2024

Alisa J. Steinhauer
Notary Public

ALISA J. STEINHAUER
Notary Public, State of Nevada
No. 13-11996-1
My Appt. Exp. July 6, 2025

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Timothy Edward Kosut Pharmacist Registration #: 14802

Pharmacy Name: Desert Winds Hospital Pharmacy

Initial each statement below to indicate you have read and agree with the following:

TK — I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

TK — I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

TK — I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

TK — I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

TK — I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		TK
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		X

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Timothy Edward Kosut
Original signature of Managing Pharmacist (copies or stamps not accepted)

3·13·24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nissim A Bejar

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

3/13/2024

Date

Board Use Only	Date Received: 3/28/24	Amount: $500-cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

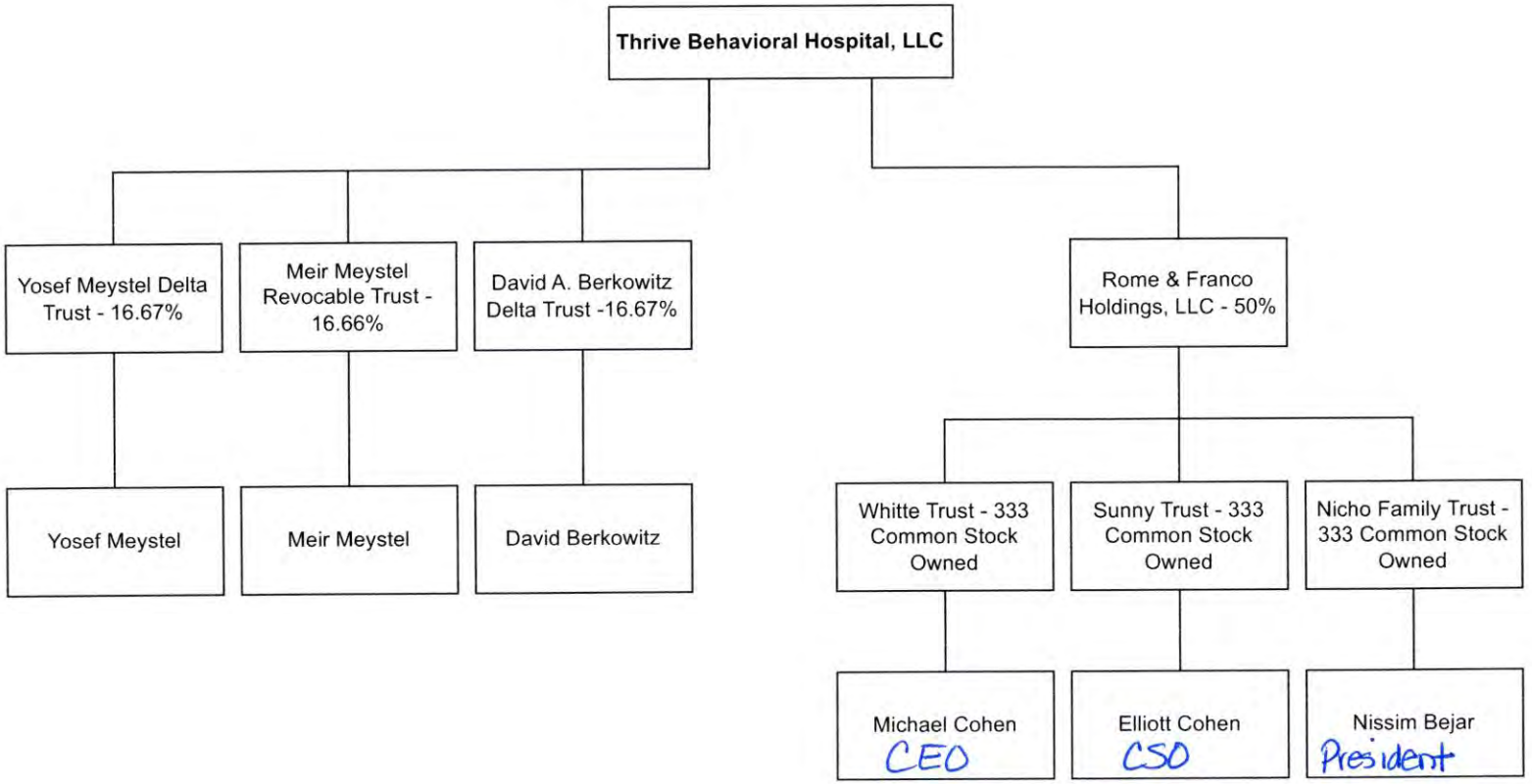
I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **Thrive Behavioral Hospital, LLC** , as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 12/29/2023, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 03/21/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202403214485980
You may verify this certificate online at http://www.nvsos.gov


Thrive Behavioral Hospital, LLC
Yosef Meystel Delta Trust - 16.67%
Meir Meystel Revocable Trust - 16.66%
David A. Berkowitz Delta Trust -16.67%
Rome & Franco Holdings, LLC - 50%
Yosef Meystel
Meir Meystel
David Berkowitz
Whitte Trust - 333 Common Stock Owned
Sunny Trust - 333 Common Stock Owned
Nicho Family Trust - 333 Common Stock Owned
Michael Cohen
CEO
Elliott Cohen
CSO
Nissim Bejar
President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Thrive Behavioral Hospital Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5900 W Rochelle Ave

City Las Vegas State NV Zip 890103

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-483-6492 Website _____

Licensing Company Email _____

Section 2: Personal Information

First Timothy Middle Edward Last Kosut

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒M ☐ F ☐ X

Mailing Address [redacted] Sky Island Dr

City Henderson State NV Zip 89002

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Shenandoah University			08/19-02/24	
Address		**City**	**State**	**Zip**
1460 University Dr		Winchester	VA	22601
Diploma/Degree obtained, if any	Currently enrolled in Non Traditional PharmD program			

School Name			From - To (MM/YY – MM/YY)	
St Francis University			08/94-06/99	
Address		**City**	**State**	**Zip**
160 St Mary St		Loretto	PA	15940
Diploma/Degree obtained, if any	Master of Business Administration			

School Name			From - To (MM/YY – MM/YY)	
Duquesne University			08/86-05/91	
Address		**City**	**State**	**Zip**
600 Forbes Ave		Pittsburgh	PA	15282
Diploma/Degree obtained, if any	BS Pharmacy			

School Name			From - To (MM/YY – MM/YY)	
Altoona Area High School			08/84-06-86	
Address		**City**	**State**	**Zip**
1415 6th Ave		Altoona	PA	16602
Diploma/Degree obtained, if any	Diploma			

School Name			From - To (MM/YY – MM/YY)	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/19-02/24	[redacted] Sky Island Dr	Henderson	NV	89002
12/18-08/19	[redacted] S Durango #2038	Las Vegas	NV	89113
06/18-12/18	[redacted] Staghorn St	Henderson	NV	89112
06/17-06/18	[redacted] Seven Hills Dr	Henderson	NV	89052
05/15-06/17	[redacted] Dow Jones St #2	Henderson	NV	89074
05/14*0515	[redacted] W Horizon Ridge #415	Henderson	NV	89052
02/12-05/14	[redacted] Driftwood Tide	Henderson	NV	89052
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Desert Winds Hospital Pharmacy			05/21-02/24	
Business Address		**City**	**State**	**Zip**
5900 West Rochelle Ave		Las Vegas	NV	89103
Phone	**Title**		**Number of Employed Hours**	
702-483-6492	DIrector of Pharmacy		3250	

Description of Duties

Managed all inpatient pharmacy activities, order verification P&T management, stocking ADM and Unit dosing, as well as developing and managing policy and procedures.

Business Name			From - To (MM/YY – MM/YY)	
Monte Vista Hospital Pharmacy			08/15-05-19	
Business Address		**City**	**State**	**Zip**
5900 W Rochelle Ave		Las Vegas	NV	89103
Phone	**Title**		**Number of Employed Hours**	
702-364-1111	Director of Pharmacy		6300	

Description of Duties

Managed all inpatient pharmacy activities, order verification P&T management, stocking ADM and Unit dosing, as well as developing and managing policy and procedures.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔ No
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3-13-2024
Date

I, Timothy Kosut, **certify that as the designated representative for**

Desert Winds Hospital Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TK I am at least 21 years of age;
3. TK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Timothy Kosut

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-13-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Timothy Kosut
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-13-2024
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Timothy Kosut, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

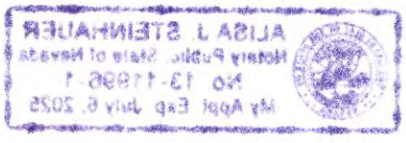
3-13-2024
Date

Subscribed and Sworn to before me this 13th day of March 2024

Alisa J. Steinhauer
Notary Public Signature

ALISA J. STEINHAUER
Notary Public, State of Nevada
No. 13-11996-1
My Appt. Exp. July 6, 2025

(Seal)


ALISA J. STEINHAUER
Notary Public, State of Nevada
No. 13-17995-1
My Appt. Exp. July 6, 2025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Thrive Behavioral Hospital, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 5900 W. Rochelle Avenue

City Las Vegas State NV Zip 89103

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Nissim Middle Alexis Last Bejar

Alias(es, nicknames, name changes, etc.) Alex

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Double Arch Court

City Las Vegas State NV Zip 89128

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Loyola University Chicago		01/09 - 12/11	
Address	**City**	**State**	**Zip**
1032 W Sheridan Rd	Chicago	IL	60660
Diploma/Degree obtained, if any			
Bachelors, Political Science			

School Name		From - To (MM/YY – MM/YY)	
Oscar Z Fasman Yeshiva Day School		09/04 -06/07	
Address	**City**	**State**	**Zip**
7135 Carpenter Rd,	Skokie	IL	60077
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/22 -03/24	[redacted]Double Arch Court	Las Vegas	NV	89128
11/21 - 06/22	[redacted]Violet Meadow Court	Las Vegas	NV	89117
03/20 - 10/21	[redacted]Crystal Creek Circle	Las Vegas	NV	89128
03/14 - 03/20	[redacted]N Kedzie Ave	Chicago	IL	60645

Section 7. Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Sandstone Healthcare Group			11/21 - 03/24
Business Address	**City**	**State**	**Zip**
7900 W Sahara Ave Suite 150	Las Vegas	NV	89117
Phone	**Title**		
7255670700	Chief Operating Officer		

Description of Duties

Oversight of management company overseeing 15 skilled nursing facilities across multiple states

Business Name			From - To (MM/YY – MM/YY)
Sapphire of Tucson			10/19 - 11/21
Business Address	**City**	**State**	**Zip**
2900 E Milber St	Tucson	AZ	85714
Phone	**Title**		
520-294-0005	Regional Director of Operations		

Description of Duties

Oversight of multiple skilled nursing facilities' operations

Business Name			From - To (MM/YY – MM/YY)
Ottawa Pavilion			08/18 - 10/21
Business Address	**City**	**State**	**Zip**
704 E Glover St	Ottawa	IL	61350
Phone	**Title**		
8154314900	Nursing Home Administrator		

Description of Duties

Administrator of 120 bed skilled nursing facility

Business Name			From - To (MM/YY – MM/YY)
Legacy Healthcare			01/14 -07/18
Business Address	**City**	**State**	**Zip**
3450 Oakton St	Skokie	IL	60076
Phone	**Title**		
847-679-9797	Administrator in training, Assistant administrator, Administrator		

Description of Duties

training leading into various roles within organization including administrator position of skilled nursing facility

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Section 8, Ques. 4 and 5

I am a managing member as well as majority member of many companies which own and operate healthcare facilities. It is common for individuals to be named in the course of their management or ownership. Other than these cases, there are no cases of which I am party to.

Lawsuits against some of these companies are related to general liability, malpractice, negligence, slip-and-fall, etc., as are expected in the industry. As a representative sample, I have provided a list of Sandstone Spring Valley, LLC's (Nevada) lawsuits. Significantly, none of the lawsuits against any of the companies I am associated with are related to controlled substances or criminal activity.

Litigation: Sandstone Spring Valley LLC

Dorothea Esposito v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Dismissed | **Case #** A-23-867681-C
Dorothy Esposito vs. Sandstone Spring Valley LLC dba Sandstone Spring Valley; DeeDee Ramon-Goodwin; Does I through X, inclusive; and Roe Corporations I through X, inclusive
Case Type: Negligence – Other Negligence
Allegations: Fall with vertebral fracture
Case Status: Settled/Dismissed with Prejudice

Donald Cloud v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case #** A-23-863971-C
Donald Edward Cloud, individually and Gino Kay Cloud Individually v. Sandstone Spring Valley LLC, Transitional Care of Las Vegas; Doe Employees 1-10 Doe Service Providers 11-20 Does 21-30; and Roe Corporations 31-40, inclusive
Case Type: Medical Malpractice
Allegations: Sacral pressure wound
Case Status: Written Discovery

Gustavo Freyre-Rodriguez v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case #** A-23-875856-C
Gustavo Lazaro Freyre-Rodriguez v. Sandstane Spring Valley, LLC dba Sandstone Spring Valley; Sandstone Healthcore Group, LLC; Mahlet Edossa Berhanu, RN; Brittany Garcia, IM APRN-CNP; Steven Dean, RN; Greny Maliakal, ID APRN-CNHP; Billie Baker, IM PA-C; Shana Tyson, LPN; Pamela Ella, LPN; Lubna Jave, M.D.; Mary Grace Rivera, APRN-CNP; Jason Regalado, APRN; Michelle Gonzalez, LPN; Laura De Fiesta, MS RD LDN; et al.
Case Type: Medical Malpractice
Allegations: Pressure wound due to bedpan usage
Case Status: Pleadings

June Lucero v. Sandstone Spring Valley: AssureCap Insurance
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case #** A-24-888873-C
June Lucero v. Sandstone Spring Valley, LLC et al.
Case Type: Negligence – Premises Liability
Allegations: Slip and Fall
Case Status: Pleadings

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/13/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nissim Bejar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/13/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Nissim A Bejar, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/13/2024

Date

Subscribed and Sworn to before me this 13th day of March 2024

Alisa J Steinhauer

Notary Public Signature

ALISA J. STEINHAUER
Notary Public, State of Nevada
No. 13-11996-1
My Appt. Exp. July 6, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Thrive Behavioral Hospital, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 5900 W. Rochelle Ave

City Las Vegas State NV Zip 89103

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Michael Middle Scott Last Cohen

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Benedict Drive

City Las Vegas State NV Zip 89161

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Chicago College of Healing Arts			
Address	**City**	**State**	**Zip**
1622 W Devon Ave	Chicago	IL	60660
Diploma/Degree obtained, if any			
Certified Massage Therpist			

School Name		From - To (MM/YY – MM/YY)	
Oakton Community College		09/2003- 06/2005	
Address	**City**	**State**	**Zip**
7701 Lincoln Ave	Skokie	IL	60077
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Ida Crown Jewish Academy		09/1997-06/2001	
Address	**City**	**State**	**Zip**
2828 W Pratt	Chicago	IL	60645
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Philip Rogers Elementary School		09/1996-06/1997	
Address	**City**	**State**	**Zip**
7345 N Washtenaw Ave	Chicago	IL	60645
Diploma/Degree obtained, if any			
Elemetary School Diploma			

School Name		From - To (MM/YY – MM/YY	
Arie Crown Herew Day School		09/1988-06/1996	
Address	**City**	**State**	**Zip**
4600 Main Street	Skokie	IL	60076
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2020-Current	[redacted] Swan Lake Ave	Las Vegas	NV	89128
06/2018-05/2020	[redacted] Van Horne Lane	Hermosa Beach	CA	90254
06-2014-05/2018	[redacted] N Keeler	Skokie	IL	60076
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Sandstone Healthcare Group			11/21-Current	
Business Address	**City**		**State**	**Zip**
7900 W Sahara Ave, Suite 150	Las Vegas		NV	89117
Phone	**Title**			
8729853773	CEO			
Description of Duties				
Manage overall day to Day operations with oversite of skilled nursing facilties.				

Business Name			From - To (MM/YY – MM/YY)	
Innovative Management Associates			10/2019-11/2021	
Business Address	**City**		**State**	**Zip**
18200 S Cicero Ave	Country Club Hills		IL	60478
Phone	**Title**			
7085731100	Regional Director Market Development			
Description of Duties				
Managing business development and oversight of admissions/marketing of skilled nursing facilties.				

Business Name			From - To (MM/YY – MM/YY)	
Legacy Healthcare			02/2018-02/2019	
Business Address	**City**		**State**	**Zip**
3450 W Oakton Ave	Skokie		IL	60076
Phone	**Title**			
8476799797	Regional Director of Business Development			
Description of Duties				
Oversight of day to day marketing and admission for skilled nursing operator.				

Business Name			From - To (MM/YY – MM/YY)	
Silicon Beach Treatment Center			06/2018-02/2019	
Business Address	**City**		**State**	**Zip**
10211 Venice Blvd	Los Angeles		CA	90034
Phone	**Title**			
(866) 520-4881	Chief Operating Officer			
Description of Duties				
Overseeing overall operations of Substance Abuse treatment center.				

Business Name			From - To (MM/YY – MM/YY)	
Legacy Healthcare			03/2016-02/2019	
Business Address	**City**		**State**	**Zip**
3450 W Oakton Ave	Skokie		IL	60076
Phone	**Title**			
8476799797	Regional Director of Business Development			
Description of Duties				
Oversight of day to day marketing and admission for skilled nursing operator.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Innovate CV			04/2014-03/2016	
Business Address		City	State	Zip
25 W 39th St 8th Floor		New York	NY	10018
Phone	Title			
3476340294	Project Manager			
Description of Duties				
Managed projects for IT department				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	✓	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1-5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/2008		IL	Chicago	Cook
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		Chicago Police Department		
Reason/Charge				
Possession				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

#1-3
In 2006 I was arrested for possession of cannabis, which I was not convicted on. In June of 2008, I was arrested for drug possession which I was granted a 2-year probation. After 2 years, I passed satisfactory and a few years later I filed for the records to be expunged. I have never been convicted of any crime, I have been outstanding citizen, community philanthropist and member of my synagogue. I am happily married for 10+ years, have 1 biological child and have guardianship/adopted 3 other children who I have been caring for ranging from 2-10 years. Additionally, I am a managing partner of 16 Healthcare facilities across 3 states (AZ, NV and UT) caring for over 1000 patients and managing approximately 1600 employees.

#4-5
We are the managing member as well as majority member of many companies which own and or operate Healthcare Facilities. It is common for individuals to be named in the course of their management and or ownership. Other than these cases, there are no cases which I am party to.

Original Signature (electronic, copies or stamps not accepted)

3/12/2024
Date

Section 8, Ques. 4 and 5

I am a managing member as well as majority member of many companies which own and operate healthcare facilities. It is common for individuals to be named in the course of their management or ownership. Other than these cases, there are no cases of which I am party to.

Lawsuits against some of these companies are related to general liability, malpractice, negligence, slip-and-fall, etc., as are expected in the industry. As a representative sample, I have provided a list of Sandstone Spring Valley, LLC's (Nevada) lawsuits. Significantly, none of the lawsuits against any of the companies I am associated with are related to controlled substances or criminal activity.

Litigation: Sandstone Spring Valley LLC

Dorothea Esposito v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Dismissed | **Case#** A-23-867681-C
Dorothy Esposito vs. Sandstone Spring Valley LLC dba Sandstone Spring Valley; ***DeeDee Ramon-Goodwin;*** *Does I through X, inclusive; and Roe Corporations I through X, inclusive*
Case Type: Negligence – Other Negligence
Allegations: Fall with vertebral fracture
Case Status: Settled/Dismissed with Prejudice

Donald Cloud v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-863971-C
Donald Edward Cloud, individually and Gina Kay Cloud Individually v. Sandstone Spring Valley LLC, Transitional Care of Las Vegas; Doe Employees 1-10 Doe Service Providers 11-20 Does 21-30; and Roe Corporations 31-40, inclusive
Case Type: Medical Malpractice
Allegations: Sacral pressure wound
Case Status: Written Discovery

Gustavo Freyre-Rodriguez v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-875856-C
Gustavo Lazaro Freyre-Rodriguez v. Sandstone Spring Valley, LLC dba Sandstone Spring Valley; Sandstone Healthcare Group, LLC; Mahlet Edossa Berhanu, RN; Brittany Garcia, IM APRN-CNP; Steven Dean, RN; Greny Maliakal, ID APRN-CNHP; Billie Baker, IM PA-C; Shana Tysan, LPN; Pamela Ella, LPN; Lubna Jave, M.D.; Mary Grace Rivera, APRN-CNP; Jasan Regalado, APRN; Michelle Gonzalez, LPN; Laura De Fiesta, MS RD LDN; et al.
Case Type: Medical Malpractice
Allegations: Pressure wound due to bedpan usage
Case Status: Pleadings

June Lucero v. Sandstone Spring Valley: AssureCap Insurance
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-24-888873-C
June Lucera v. Sandstane Spring Valley, LLC et al.
Case Type: Negligence – Premises Liability
Allegations: Slip and Fall
Case Status: Pleadings

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Cohen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Michael Scott Cohen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/12/2024

Date

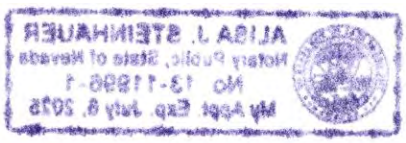
Subscribed and Sworn to before me this 12th day of March 2024

Alisa J. Steinhauer

Notary Public Signature

ALISA J. STEINHAUER
Notary Public, State of Nevada
No. 13-11996-1
My Appt. Exp. July 6, 2025

(Seal)


ALICIA J. STEINHAUER
Notary Public, State of Nevada
No. 13-11856-1
My Appt. Exp. July 8, 2015

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Thrive Behavioral Hospital

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 5900 W. Rochelle Ave.

City Las Vegas State NV Zip 89103

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Elliott Middle David Last Cohen

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] W. Patrick Lane

City Las Vegas State NV Zip 89118

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Oakton Community College		9/2003-6/2004	
Address	**City**	**State**	**Zip**
7701 Lincoln Ave	Skokie	IL	60077
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Ida Crown Jewish Academy		9/1997-6/2001	
Address	**City**	**State**	**Zip**
2828 W. Pratt	Chicago	IL	60645
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Phillip Rogers Elementary School		09/1996-06/1997	
Address	**City**	**State**	**Zip**
7345 N Washtenaw Ave	Chicago	IL	60645
Diploma/Degree obtained, if any			
Elementary School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Arie Crown Hebrew Day School		09/1988-06/1996	
Address	**City**	**State**	**Zip**
4600 Main Street	Skokie	IL	60076
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2022-current	[redacted] W. Patrick Lane	Las Vegas	NV	89118
09/2020-04/2022	[redacted] Canyon Breeze	Las Vegas	NV	89134
09/2019-09/2020	[redacted] Dove River Road	Las Vegas	NV	89134
10/2000-09/2019	[redacted] N. Central Park Ave	Chicago	IL	60659
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Sandstone Healthcare Group			11/21-current	
Business Address	**City**		**State**	**Zip**
7900 W. Sahara Ave Suite 150	Las Vegas		NV	89117
Phone	**Title**			
702-724-3116	CSO			
Description of Duties				
Manage Strategic company decisions, Company wide purchasing,Marketing and Buiness development initiatives,and Plant operations.				

Business Name			From - To (MM/YY – MM/YY)	
Innovative Management Associates			10/2019-11/2021	
Business Address	**City**		**State**	**Zip**
18200 S. Cicero Ave	Country Club Hills		IL	60478
Phone	**Title**			
708-573-1100	Regional Director of Market Developement			
Description of Duties				
Oversight of daily Buisness Developement and marketing for patients's transition for Long term care facility operators and Day to Day Operations Consulting.				

Business Name			From - To (MM/YY – MM/YY)	
Citadel Healthcare			10/2018-10/2019	
Business Address	**City**		**State**	**Zip**
9615 Knox Ave	Skokie		IL	60076
Phone	**Title**			
847-679-4161	Regional Director of Market Developement			
Description of Duties				
Oversight of daily Buisness Developement and marketing for patients's transition for Long term care facility operators.				

Business Name			From - To (MM/YY – MM/YY)	
Legacy Healthcare			10/2015-10/2018	
Business Address	**City**		**State**	**Zip**
3450 Oakton Street	Skokie		IL	60076
Phone	**Title**			
847-679-9797	Regional Director of Business Developement			
Description of Duties				
Oversight of daily Buisness Developement and marketing for patients's transition for Long term care facility operators.				

Business Name			From - To (MM/YY – MM/YY)	
Premiere Distribution LLC.			01/2014-10/2015	
Business Address	**City**		**State**	**Zip**
7305 Saint Louis Ave	Skokie		IL	60076
Phone	**Title**			
224-534-7525	Director of Sales			
Description of Duties				
Develop Strong relationships with Clients andensure accounts are servicesd in timely fashion. Drive revenue and evaluate account profitablity and Margins. Oversee work order transitions and office expenses to maintain annual budget.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	✓	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1-5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/2008		IL	Chicago	Cook
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		Chicago Police Department		
Reason/Charge				
Possession				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

#1-3
In 2008, I was arrested for drug possession. I had a 2 year probation period which I completed with satifactory status. Since then, I have had a clean record and have undergone multiple backround checks, which have all been clear. I currently own and operate 15 Skilled nursing facilities in multiple states. We have over 1500 employees and care for over 1000 patients on a day basis. I am a contributing member to the Las Vegas Community, as well as our local synogogue, community and several charitable organizations throughout the United states. I have been happily married for 8 years and have 2 wonderful children under the age of 7.

#4-5
I am a managing member as well as majority member of many companies which own and operate healthcare facilities. It is common for individuals to be name in the course of their management or ownership. Other than these cases, there are no cases of which I am party to.



Original Signature (electronic, copies or stamps not accepted)

03/12/2024

Date

Section 8, Ques. 4 and 5

I am a managing member as well as majority member of many companies which own and operate healthcare facilities. It is common for individuals to be named in the course of their management or ownership. Other than these cases, there are no cases of which I am party to.

Lawsuits against some of these companies are related to general liability, malpractice, negligence, slip-and-fall, etc., as are expected in the industry. As a representative sample, I have provided a list of Sandstone Spring Valley, LLC's (Nevada) lawsuits. Significantly, none of the lawsuits against any of the companies I am associated with are related to controlled substances or criminal activity.

Litigation: Sandstone Spring Valley LLC

Dorothea Esposito v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Dismissed | **Case#** A-23-867681-C
Dorothy Esposito vs. Sandstone Spring Valley LLC dba Sandstone Spring Valley; ***DeeDee Ramon-Goodwin****; Does I through X, inclusive; and Roe Corporations I through X, inclusive*
Case Type: Negligence – Other Negligence
Allegations: Fall with vertebral fracture
Case Status: Settled/Dismissed with Prejudice

Donald Cloud v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-863971-C
Donald Edward Cloud, individuolly and Gina Kay Cloud Individually v. Sandstone Spring Valley LLC, Transitional Care of Las Vegas; Doe Employees 1-10 Doe Service Providers 11-20 Does 21-30; and Roe Corporations 31-40, inclusive
Case Type: Medical Malpractice
Allegations: Sacral pressure wound
Case Status: Written Discovery

Gustavo Freyre-Rodriguez v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-875856-C
Gustavo Lazaro Freyre-Rodriguez v. Sandstone Spring Valley, LLC dba Sandstone Spring Valley; Sandstone Healthcare Group, LLC; Mahlet Edossa Berhanu, RN; Brittany Garcia, IM APRN-CNP; Steven Dean, RN; Greny Maliakal, ID APRN-CNHP; Billie Boker, IM PA-C; Shana Tyson, LPN; Pamela Ella, LPN; Lubna Jave, M.D.; Mary Grace Rivera, APRN-CNP; Jason Regalado, APRN; Michelle Gonzalez, LPN; Laura De Fiesta, MS RD LDN; et al.
Case Type: Medical Malpractice
Allegations: Pressure wound due to bedpan usage
Case Status: Pleadings

June Lucero v. Sandstone Spring Valley: AssureCap Insurance
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-24-888873-C
June Lucero v. Sondstone Spring Valley, LLC et al.
Case Type: Negligence – Premises Liability
Allegations: Slip and Fall
Case Status: Pleadings

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Elliott Cohen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Elliott David Cohen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/12/24

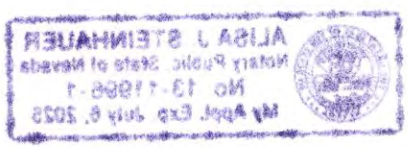
Date

Subscribed and Sworn to before me this 12th day of March 2024

Notary Public Signature

ALISA J. STEINHAUER
Notary Public, State of Nevada
No. 13-11996-1
My Appt. Exp. July 8, 2025

(Seal)


ALISA J STEINHAUER
Notary Public State of Nevada
No. 13-17868-1
My Appt. Exp. July 6, 2025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Thrive Behavioral Hospital, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 5900 W. Rochelle Ave

City: Las Vegas State: NV Zip: 89103

Mailing Address (if different from physical address): 4635 CHASE AVE

City: LINCOLNWOOD State: IL Zip: 60712

Telephone: 847-267-3800 Website:

Licensing Company Email:

Section 2: Personal Information

First: David Middle: Last: Berkowitz

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] N. FRANCISCO

City: CHICAGO State: IL Zip: 60645

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/17 Present	[redacted] N. Francisco	Chicago	IL	60645
From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/04 09/17	W Fitch	Chicago	IL	60645
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	X	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	X	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/11/24
Date

Section 8, Ques. 4 and 5

I am a managing member as well as majority member of many companies which own and operate healthcare facilities. It is common for individuals to be named in the course of their management or ownership. Other than these cases, there are no cases of which I am party to.

Lawsuits against some of these companies are related to general liability, malpractice, negligence, slip-and-fall, etc., as are expected in the industry. As a representative sample, I have provided a list of Sandstone Spring Valley, LLC's (Nevada) lawsuits. Significantly, none of the lawsuits against any of the companies I am associated with are related to controlled substances or criminal activity.

Litigation: Sandstone Spring Valley LLC

Dorothea Esposito v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Dismissed | **Case#** A-23-867681-C
*Dorothy Esposito vs. Sondstone Spring Volley LLC dbo Sondstone Spring Valley; **DeeDee Ramon-Goodwin**; Does I through X, inclusive; and Roe Corporations I through X, inclusive*
Case Type: Negligence – Other Negligence
Allegations: Fall with vertebral fracture
Case Status: Settled/Dismissed with Prejudice

Donald Cloud v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-863971-C
Donald Edward Cloud, individually and Gina Kay Cloud Individually v. Sandstane Spring Valley LLC, Transitional Care of Las Vegos; Dae Employees 1-10 Doe Service Providers 11-20 Does 21-30; and Roe Corporations 31-40, inclusive
Case Type: Medical Malpractice
Allegations: Sacral pressure wound
Case Status: Written Discovery

Gustavo Freyre-Rodriguez v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-875856-C
Gustavo Lazoro Freyre-Rodriguez v. Sandstone Spring Valley, LLC dba Sandstane Spring Valley; Sandstane Healthcare Group, LLC; Mahlet Edassa Berhanu, RN; Brittany Garcia, IM APRN-CNP; Steven Dean, RN; Greny Maliakal, ID APRN-CNHP; Billie Baker, IM PA-C; Shana Tysan, LPN; Pamela Ella, LPN; Lubna Jave, M.D.; Mary Grace Rivera, APRN-CNP; Jasan Regalado, APRN; Michelle Gonzalez, LPN; Laura De Fiesta, MS RD LDN; et al.
Case Type: Medical Malpractice
Allegations: Pressure wound due to bedpan usage
Case Status: Pleadings

June Lucero v. Sandstone Spring Valley: AssureCap Insurance
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-24-888873-C
June Lucero v. Sandstone Spring Valley, LLC et al.
Case Type: Negligence – Premises Liability
Allegations: Slip and Fall
Case Status: Pleadings

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Berkowitz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/11/24

Date

Please have this section completed in the presence of a Notary Public.

State of IL, ss. County of COOK

I, DAVID BERKOWITZ, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/11/24

Date

Subscribed and Sworn to before me this 11 day of March 2024.

Notary Public Signature

FREDERICK S FRANKEL
Official Seal
Notary Public - State of Illinois
My Commission Expires Oct 23, 2025

(Seal)

DAVID BERKOWITZ

[redacted] W. Francisco
Chicago IL 60645
[redacted]

EDUCATION:

- Graduate School- Long Island University -
  Masters- Healthcare Administrator-1998

WORK HISTORY:

- Coastline Transportation-1998-December 2002
- Care Centers- Administrator-January 1 2003-June 2005
- Platinum Health Care-Administrator-July 2005-June 2007

CURRENT EMPLOYMENT:

- Yam Management-Partner- July 2007- July 2014
- Aperion Care, Inc-Partner- July 2014- Present

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Thrive Behavioral Hospital, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 5900 W. Rochelle Ave

City: Las Vegas State: NV Zip: 89103

Mailing Address (if different from physical address): 4655 CHASE AVE

City: LINCOLNWOOD State: IL Zip: 60712

Telephone: 847-262-3800 Website:

Licensing Company Email:

Section 2: Personal Information

First: Yosef Middle: Last: Meystel

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] CHASE AVE

City: LINCOLNWOOD State: IL Zip: 60712

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

See Attached Resume

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2011 – Present	[redacted] N. St. Louis	Chicago	IL	60639
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

See attached resume

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

YOSEF MEYSTEL

[redacted]N. ST. LOUIS AVE. CHICAGO, IL 60659 [redacted]

EXPERIENCE

2014 – Present Aperion Care, Inc. Lincolnwood, IL

- Principal of company which provides operational assistance to long term care facilities

2006 – 2014 YAM Management Skokie, IL

- Management and Operational oversight for long term care facilties

2000 - 2006 EMI / EKS Management Lincolnwood, IL

Administrator

- Responsible for daily operations of the nursing home
- Managed 150 Employees
- Increased revenues each year by 10%

1997 - 2000 Brightview Care Center Chicago, IL

Assistant Administrator

- Assistant to the Administrator

EDUCATION

1997 Riff Rabbinacal College South Bend, IN

- B.A., Business Administration and Computer Science.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	X	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	X	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/11/24
Date

Section 8, Ques. 4 and 5

I am a managing member as well as majority member of many companies which own and operate healthcare facilities. It is common for individuals to be named in the course of their management or ownership. Other than these cases, there are no cases of which I am party to.

Lawsuits against some of these companies are related to general liability, malpractice, negligence, slip-and-fall, etc., as are expected in the industry. As a representative sample, I have provided a list of Sandstone Spring Valley, LLC's (Nevada) lawsuits. Significantly, none of the lawsuits against any of the companies I am associated with are related to controlled substances or criminal activity.

Litigation: Sandstone Spring Valley LLC

Dorothea Esposito v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Dismissed | **Case#** A-23-867681-C
Dorothy Esposito vs. Sandstone Spring Valley LLC dba Sandstone Spring Valley; ***DeeDee Ramon-Goodwin****; Does I through X, inclusive; and Roe Corporations I through X, inclusive*
Case Type: Negligence – Other Negligence
Allegations: Fall with vertebral fracture
Case Status: Settled/Dismissed with Prejudice

Donald Cloud v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-863971-C
Danald Edward Cloud, individually and Gina Kay Claud Individually v. Sandstone Spring Valley LLC, Transitional Care of Las Vegas; Doe Employees 1-10 Doe Service Providers 11-20 Does 21-30; and Roe Corporations 31-40, inclusive
Case Type: Medical Malpractice
Allegations: Sacral pressure wound
Case Status: Written Discovery

Gustavo Freyre-Rodriguez v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-875856-C
Gustavo Lazaro Freyre-Rodriguez v. Sandstone Spring Valley, LLC dba Sandstone Spring Valley; Sandstone Healthcare Group, LLC; Mahlet Edassa Berhanu, RN; Brittany Garcia, IM APRN-CNP; Steven Dean, RN; Greny Maliakal, ID APRN-CNHP; Billie Baker, IM PA-C; Shana Tysan, LPN; Pamela Ella, LPN; Lubna Jave, M.D.; Mary Grace Rivera, APRN-CNP; Jasan Regalado, APRN; Michelle Ganzalez, LPN; Laura De Fiesta, MS RD LDN; et al.
Case Type: Medical Malpractice
Allegations: Pressure wound due to bedpan usage
Case Status: Pleadings

June Lucero v. Sandstone Spring Valley: AssureCap Insurance
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-24-888873-C
June Lucero v. Sandstone Spring Valley, LLC et al.
Case Type: Negligence – Premises Liability
Allegations: Slip and Fall
Case Status: Pleadings

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yosef Meystel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/11/24

Date

Please have this section completed in the presence of a Notary Public.

State of IL, ss. County of Cook

I, YOSEF Meystel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/11/24

Date

Subscribed and Sworn to before me this 11th day of March 2024

Notary Public Signature

FREDERICK S FRANKEL
Official Seal
Notary Public - State of Illinois
My Commission Expires Oct 23, 2025

FREDERICK S FR
Official Se
Notary Public - Stat
My Commission Expire

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Thrive Behavioral Hospital, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (If applicable): _____

Physical Address: 5900 W. Rochelle Ave

City: Las Vegas State: NV Zip: 89103

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: Meir Middle: Simcha Last: Meystel

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Collins Ave [redacted]

City: Miami Beach State: FL Zip: 33140

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Collage of Dupage				
Address		City	State	Zip
Diploma/Degree obtained, if any				
GED				
School Name			From - To (MM/YY – MM/YY)	
Yeshiva Teferis Bachorim			9/03-5/04	
Address		City	State	Zip
		Monsey	NY	
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
Ohr Chodesh			9/02/6/03	
Address		City	State	Zip
		Lakewood	NJ	
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
Yeshiva of Belle Harbor				
Address		City	State	Zip
		Belle Harbor	NY	
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/23-Current	[redacted] Collins Ave [redacted]	Miami Beach	FL	33140
7/22-5/23	[redacted] W 51st Street	Miami Beach	FL	33140
1/20-7/22	[redacted] Keeler Ave	Skokie	IL	60076
2/15-1/20	[redacted] N Trumbull Ave	Lincolnwood	IL	60712
10/12-2/15	[redacted] N St Louis Ave	Lincolnwood	IL	60712
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SandStone Healthcare Group			10/2021-Current
Business Address	**City**	**State**	**Zip**
7900 W Sahara Ace Suite 150	Las Vegas	NV	89117
Phone	**Title**		
725-567-0700	President		
Description of Duties			
Assist CEO and others in day to day operations of nursing facilities			

Business Name			From - To (MM/YY – MM/YY)
Elevate Care			1/19- current
Business Address	**City**	**State**	**Zip**
4655 W Chase Ave	Lincolnwood	IL	60712
Phone	**Title**		
847-262-3800	CEO & President		
Description of Duties			
assist COO and other corporate staff on day to day operations of nursing facilities			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8, Ques. 4 and 5

I am a managing member as well as majority member of many companies which own and operate healthcare facilities. It is common for individuals to be named in the course of their management or ownership. Other than these cases, there are no cases of which I am party to.

Lawsuits against some of these companies are related to general liability, malpractice, negligence, slip-and-fall, etc., as are expected in the industry. As a representative sample, I have provided a list of Sandstone Spring Valley, LLC's (Nevada) lawsuits. Significantly, none of the lawsuits against any of the companies I am associated with are related to controlled substances or criminal activity.

Litigation: Sandstone Spring Valley LLC

Dorothea Esposito v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Dismissed | **Case#** A-23-867681-C
Dorothy Esposito vs. Sandstone Spring Valley LLC dba Sandstone Spring Valley; ***DeeDee Ramon-Goodwin****; Does I through X, inclusive; and Roe Corparations I through X, inclusive*
Case Type: Negligence – Other Negligence
Allegations: Fall with vertebral fracture
Case Status: Settled/Dismissed with Prejudice

Donald Cloud v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-863971-C
Donald Edward Claud, individually and Gina Kay Cloud Individually v. Sandstone Spring Valley LLC, Transitional Care of Las Vegas; Doe Employees 1-10 Doe Service Providers 11-20 Does 21-30; and Rae Carporations 31-40, inclusive
Case Type: Medical Malpractice
Allegations: Sacral pressure wound
Case Status: Written Discovery

Gustavo Freyre-Rodriguez v. Sandstone Spring Valley: HPLTC
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-23-875856-C
Gustavo Lazaro Freyre-Radriguez v. Sandstone Spring Valley, LLC dba Sandstone Spring Valley; Sandstone Healthcare Group, LLC; Mahlet Edossa Berhanu, RN; Brittany Garcia, IM APRN-CNP; Steven Dean, RN; Greny Maliakal, ID APRN-CNHP; Billie Baker, IM PA-C; Shana Tysan, LPN; Pamela Ella, LPN; Lubna Jave, M.D.; Mary Grace Rivera, APRN-CNP; Jasan Regalado, APRN; Michelle Gonzalez, LPN; Laura De Fiesta, MS RD LDN; et al.
Case Type: Medical Malpractice
Allegations: Pressure wound due to bedpan usage
Case Status: Pleadings

June Lucero v. Sandstone Spring Valley: AssureCap Insurance
Eighth Judicial District Court, Clark County, Nevada
Case Status: Open | **Case#** A-24-888873-C
June Lucera v. Sandstone Spring Valley, LLC et al.
Case Type: Negligence – Premises Liability
Allegations: Slip and Fall
Case Status: Pleadings

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Meir Meystel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

~~3/6/2024~~ 3/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami Dade

I, Meir Simcha Meytel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

MARCH 12th, 2024

Date

Subscribed and Sworn to before me this 12th day of March/2024.

Dora Camps

Notary Public Signature

DORA CAMPS
Notary Public - State of Florida
Commission # HH 411588
My Comm. Expires Jun 15, 2027
Bonded through National Notary Assn.

(Seal)

NUTILE LAW

Maria Nutile, Esq.*
Bridget Kelly, Esq. **

* licensed in NV, AZ and CO
** licensed in NV and AZ

March 27, 2024

VIA FEDEX

Mark Sedar, COO
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste. 206
Reno, NV 89521

Re: Change of Ownership Application
Thrive Behavioral Hospital, LLC, # IB02706

Dear Mr. Sedar:

This firm represents Thrive Behavioral Hospital LLC ("Thrive"). Enclosed please find Thrive's change of ownership application ("Application") for the pharmacy at Desert Winds Hospital, current license no. IB02706, located at 5900 W. Rochelle Avenue, Las Vegas ("Hospital"). We request that this Application be considered at the Nevada State Board of Pharmacy's ("BOP") meeting on May 29-30, 2024 in Las Vegas.

Thrive has entered into an agreement to purchase certain assets of the Hospital, including its licenses, to be effective once all necessary licenses and permits are in place. Thrive plans to continue using the Hospital's current consultant, Brian Bulfer with Advanced Pharmaceutical Consultants, after it assumes ownership.

As referenced in the enclosed Personal History Applications, several of the individual indirect owners of Thrive are also members of many other companies which own and operate healthcare facilities, primarily skilled nursing facilities, in various states. These other entities are parties to numerous lawsuits related to general liability, malpractice, negligence, slip-and-fall, etc., as are expected in the industry. As a list of all business entities and their related lawsuits would be unwieldy, Thrive has provided a list of Sandstone Spring Valley, LLC's (Nevada) lawsuits as representative of the lawsuits faced by their other entities. Significantly, none of the lawsuits are related to controlled substances or criminal activity.

Finally, please note that records related to Elliott Cohen's and Michael Cohen's criminal cases in 2006 and 2008 were expunged and are unavailable through court records. They are also no longer available from their former attorneys. The Cohens assure the BOP that the arrests were

7395 S. Pecos Rd. · Suite 103 · Las Vegas, Nevada 89120
Phone: (702) 307-4880 · Fax: (702) 307-4881
www.nutilelaw.com

related to young adult antics, and are not indicative of any current substance abuse issues or representative of their character and integrity.

Should you have any questions, I may be reached at 702.307.4870 or via email at maria@nutilelaw.com.

Sincerely,

NUTILE LAW

Maria Nutile

Maria Nutile, Esq.

Encl.

cc: Thrive Behavioral Hospital LLC

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

y

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: OSRX, Inc. #2675

Physical Address: 2675 Palmer Street Suite D.

City: Missoula State: MT Zip: 59808

Mailing Address (if different from physical address): 1120 Kensington Ave. Suite E

City: Missoula State: MT Zip: 59801

Telephone: 406-541-6121 Toll Free # (NAC 639.708, NRS 639.23286): 1-855-484-9696

Fax: 406-493-0471 Contact Email: info@osrxpharmaceuticals.com

Website: www.osrxpharmaceuticals.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Jasmine Lee Olson

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24092

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jasmine Lee Olson	NV Pharmacist Registration #: 24092
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): OSRX, Inc.

Corporation/Organization Name: OSRX, Inc.

Mailing Address: 1120 Kensington Ave. Suite E.

City: Missoula State: MT Zip: 59801

Telephone: 406-541-6121 Email: info@osrxpharmaceuticals.com

Contact Person Name: Anthony Sampietro

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

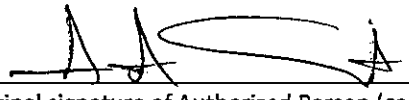
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for OSRX, Inc. #2675 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Anthony Sampietro

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

5/9/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Anthony Sampietro hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner (title) for OSRX, Inc. #2675 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

Please see attached California Jurat

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

Signature of Document Signer No. 1

Signature of Document Signer No. 2 (if any)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 23rd (Date) day of May (Month), 2024 (Year), by
(1) Anthony Sampietro
(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ROBIN J. FOSSELMAN
Notary Public - California
Los Angeles County
Commission # 2410413
My Comm. Expires Aug 3, 2026

Signature Robin J. Fosselman
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

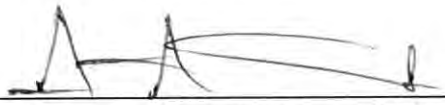
Description of Attached Document
Title or Type of Document: Affidavit for Pharmacy License **Document Date:** _____
Number of Pages: _____ **Signer(s) Other Than Named Above:** _____

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I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anthony Sampietro Owner

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

5/9/24

Date

Board Use Only	Date Received: 5/29/24	Amount: $500 cc

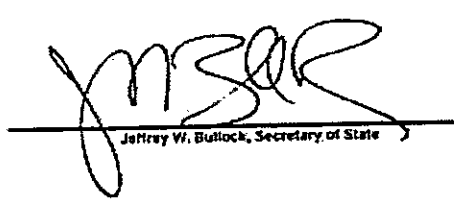
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OSRX, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "OSRX, INC." WAS INCORPORATED ON THE TWENTY-SEVENTH DAY OF APRIL, A.D. 2018.





6862461 8300

SR# 20242005270

Authentication: 203442414

Date: 05-09-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Montana Department of
LABOR & INDUSTRY

Montana Department of Labor and Industry
Employment Standards Division
301 South Park Ave
Helena MT, 59620

Montana Board of Pharmacy
On-Site Inspection Report

License Number: PHA-PHR-LIC-103076	**Licensee Name:** OSRX INC #2675
Licensee Address and Phone Number: 2675 PALMER STE D, MISSOULA 855-484-9696	**Pharmacist-in-charge Name and Email:** Jamine Olson jlolson@osrxpharmaceuticals.com
Inspection Date: 05-10-2024	**Inspector Name:** Genine Pitts, PharmD
Inspector E-mail: genine.pitts@mt.gov	**Inspector Phone:** 406-431-1952
Inspection Type: ☑ **Initial** ☐ **Annual** ☐ **Re-Inspection**	**Inspection Status:** ☑ **Passed** ☐ **Failed** ☐ **Passed with Conditions**

Comments:

This was the initial inspection and the pharmacy is not yet operational. Security, workflow areas, storage areas, and policies/procedures for dispensing activity were reviewed. The facility will be purchasing sterile eye drops from the co-owned FDA registered 503B compounding pharmacy, license PHA-WDD-LIC-103074 and PHA-PHR-LIC-58632, for dispensing pursuant to a prescription. They will fulfill patient orders and ship to patients in Montana. They are pursuing licensing as a Mail Order Pharmacy in other states.

Note that neither remote nor on-site Board inspections evaluate compliance with all requirements.

Links to REFERENCE information: ARM and MCA

Montana Department of
LABOR & INDUSTRY

Montana Board of Pharmacy Inspection Form – On-site
Community Pharmacy (PHR)

PHARMACY FACILITY

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Is the pharmacy orderly and clean?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.819(1)	The facility is not yet operational and no pharmaceuticals were on-site during the inspection. Workflow areas and storage areas are sufficient for planned operation.
Are the sanitation and equipment requirements met?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.819(2)	Reviewed workspace areas and storage areas (no pharmaceuticals were on-site at this time).
Are the security requirements of the pharmacy being met?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.814	Auto-lock door with keycard access by authorized personnel. Camera. VPN and secure log-in for dispensing software.
Is the mandated generic substitution sign displayed?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	MCA 37-7-506	Posted near entrance.
Does the pharmacy access a common electronic file?	☐ YES ☑ N/A	ARM 24.174.840	
If the pharmacy accesses a common electronic file, are the required notices in place?	☐ YES ☐ NO ☑ N/A	ARM 24.174.840(6)	
What pharmacy dispensing systems are utilized?	☐ N/A LIST>	ARM 24.174.1122	*Provide the name of the system or systems.* Life File
Are secure/unique login credentials kept for the pharmacy dispensing system?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.817(1)	Reviewed security of remote access to database by appropriate personnel. Every function is recorded and traceable in the system.
Is the pharmacy providing services to other facilities?	☐ YES LIST> ☑ N/A		*List:*

Does the pharmacy utilize centralized filling and processing of drug order services?	☐ YES LIST> ☑ N/A		*List:*
If the pharmacy is utilizing central filling and processing of drug orders, are all the requirements being met?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.823	
Does the pharmacy utilize remote processing of drug orders?	☑ YES LIST> ☐ N/A		*List:* Remote processing services at other Palmer license (PHA-PHR-LIC-88693)
If the pharmacy is utilizing remote processing of drug orders, are all the security requirements being met?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	ARM 24.174.814 ARM 24.174.818	Common ownership.
Are outdated pharmaceuticals removed from stock and processed as required?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.2301(1)	Unable to evaluate. No pharmaceuticals present at time of inspection. Reviewed operation policies for returning/destroying unused pharmaceuticals.
Are the pharmaceuticals stored properly?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.819	Storage room has temperature and humidity monitors.
Can the system produce a drug audit?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.818(1)	
Is the pharmacy registered with the Montana Prescription Drug Registry (MPDR)?	☑ YES ☐ NO ☐ N/A	ARM 24.174.1704(4)	
Is the pharmacy reporting required information to the MPDR by the close of the next business day?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1704(2)	Exempt from reporting (no controlled substances dispensed).
Is the Pharmacist-in-Charge (PIC) verifying the reported MPDR data as required?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.1704(6)	N/A

LICENSING AND ENDORSEMENTS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Is the current facility license posted in a conspicuous place?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	MCA 37-7-321	Reviewed
Is the Montana Dangerous Drug registration current?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1401(2)	N/A
Are facility endorsements appropriate for facility?	☑ YES ☐ NO ☐ N/A		Technician Utilization Plan
Is the facility DEA registration current?	☐ YES ☐ NO ☑ N/A	21 CFR 1301.11	*Expiration date:* N/A
Is the Combat Methamphetamine Self Certification current?	☐ YES ☐ NO ☑ N/A	21 CFR 1314.40	*Expiration date:* N/A
Do all pharmacists, interns, and technicians have an active license?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	MCA 37-7-301	Reviewed
Do the certified technicians have a current certification?	☑ YES ☐ NO	MCA 37-7-301	Posted and current
Has the PIC verified current employment and address information?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.301(34)	When there is a change in employment or address, contact Liz at ecarney@mt.gov with updates.
Are endorsements on the pharmacists' licenses appropriate for site activities?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT		
Do the pharmacists have a current CPR certificates?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.503(3)	N/A: No vaccine administration.

DISPENSING ACTIVITIES

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Are the pharmacists identified?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	MCA 37-7-101(32)	Not yet operational, will evaluate during the next inspection.
Is every prescription order evaluated by a pharmacist for safety and therapeutic appropriateness?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.1104(1)	Reviewed description of operations and prescription dispensing/verification activities.
Does the pharmacist perform prospective drug review?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.902	Life File
Does the pharmacist counsel patients as required?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.903	Discussed process with Jasmine.
Is there an appropriate counseling area?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.903(2)	*Describe the area or areas where counseling takes place.* Private conference room is available.
Are the prescriptions properly labeled?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.832	N/A: Not operational at time of inspection.
Are you compounding at this facility?	☐ YES LIST> ☑ N/A		*List the types of compounding:*
Are you compounding nonsterile pharmaceutical preparations?	☐ YES LIST> ☑ N/A		*List up to three examples:*
Are policies and procedures in place to meet the requirements of USP 795 Compounding-Nonsterile pharmaceutical products?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.841(9)	

Are you compounding sterile pharmaceutical preparations?	☐ YES LIST> ☑ N/A		*List up to three examples:*
Are policies and procedures in place to meet the requirements of USP 797 Compounding-Sterile pharmaceutical products?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.841(9)	
Are policies and procedures in place to meet the requirements of USP 800 Hazardous Drugs-Handling in Healthcare Settings?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.2301(1)	No hazardous drug handling
Is the assessment of risk for hazardous drugs current?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	USP 800 / ARM 24.174.2301(1)	No hazardous drug handling
Is there a quality assurance program in place?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.407	*What is the last date of the program review?* Not evaluated: Facility not yet operational.

PRESCRIPTION REQUIREMENTS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Do the prescriptions contain the required information?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.831	Not evaluated: Facility not yet operational.
Are prescription transfers properly documented?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT	ARM 24.174.835	Not evaluated: Facility not yet operational.
Do the Schedule III-V phoned in prescriptions contain the required information?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT	21 CFR 1306.05	N/A: No controlled substances.

RECORD KEEPING

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Are the Power of Attorney forms in place for current staff to order controlled substances?	☐ YES ☐ NO ☑ N/A	21 CFR 1305.05	*How many individuals at the facility are authorized to order controlled substances?* N/A
Are the PIC agreements in place?	☑ YES ☐ NO	ARM 24.174.805	
Are individual DEA CSOS key codes kept confidential?	☐ YES ☐ NO ☑ N/A	21 CFR 1311.30	N/A
Are DEA 222 forms properly executed?	☐ YES ☐ NO ☑ N/A	21 CFR 1305.12	N/A
Is the DEA Biennial Inventory current, correctly formatted, and available?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	21 CFR 1304.11	N/A
Are the controlled substance invoices filed properly?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	21 CFR 1304.21	N/A
Are Schedule II records filed separately?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	21 CFR 1304.04(h)1	N/A
Are controlled substance prescriptions filed properly?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	21 CFR 1304.04(h)1	N/A
Does the pharmacy maintain perpetual inventory on Schedule II drugs?	☐ YES ☐ NO ☑ N/A	ARM 24.174.814(1)	N/A

Is the perpetual inventory reconciled as required?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.814(1)	N/A
Have there been any significant shortages or losses of controlled substances in the past year?	☐ YES ☑ N/A	21 CFR 1301.74(c)	N/A
If so, was the loss reported to the DEA within 24 hours, the Board of Pharmacy, and law enforcement?	☐ YES ☐ NO ☑ N/A	21 CFR 1301.74(c) ARM 24.174.1411(3), (4)	*Date of loss:* *Date the Board was notified:*

PHARMACY TECHNICIANS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Is the Technician Utilization Plan accessible and being used?	☑ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	ARM 24.174.712	Dated 11-15-23
Has the Technician Utilization Plan been annually reviewed and current?	☑ YES ☐ NO ☐ N/A	MCA 37-7-308(1)	Dated 11-15-23
Do the technicians and auxiliary staff understand their responsibilities and limitations?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☐ N/A	ARM 24.174.705	Not evaluated: Facility not yet operational.
Are the technicians and auxiliary staff properly identified?	☐ YES ☐ NO ☑ N/A	ARM 24.174.703(5)	Not evaluated: Facility not yet operational.
Are the technicians properly identifying themselves when answering the telephone?	☐ YES ☐ NO ☑ N/A	ARM 24.174.705(1)	Not evaluated: Facility not yet operational.
What is the current technician ratio?	☐ YES ☐ NO ☑ N/A	ARM 24.174.711	*Describe the typical staffing levels.*

Does the pharmacy operate with a technician variance approved by the Board?	☐ YES ☐ NO ☑ N/A	ARM 24.174.711(3)	*What is the effective date and approved variance date?* *Approved variance:* *Approved Date:*
If an application for increased ratio has been requested, are the required documents in place?	☐ YES ☐ NO ☑ N/A	ARM 24.174.711(4)	

PHARMACY INTERNS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Does the preceptor/intern relationship meet requirements?	☐ YES ☐ NO ☑ N/A	ARM 24.174.602	

ADMINISTRATION OF VACCINES

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Does the pharmacy limit immunizations to the independent authority allowed in statute?	☐ YES ☐ NO ☑ N/A	MCA 37-7-105	*What additional immunizations are allowed under a collaborative agreement?*
Are the required policies and procedures for the immunization program in place?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.503(4)	
Is there access to the CDC reference?	☐ YES ☐ NO ☑ N/A	ARM 24.174.503(4)	
Are the required state sanctioned immunization records complete and maintained?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	MCA 37-7-105(4)	

COLLABORATIVE PRACTICE

		REFERENCE	CORRECTIVE ACTION/COMMENTS
List of current collaborative practice agreements:	☑ N/A LIST>		*List the type of agreement and the effective date.*
Have all participating staff signed the current collaborative practice agreements?	☐ YES ☐ NO ☑ N/A	ARM 24.174.524(2)	
Do the collaborative practice agreements include all requirements?	☐ YES ☐ NO ☑ N/A	ARM 24.174.524(2)	

TELEPHARMACY OPERATIONS

		REFERENCE	CORRECTIVE ACTION/COMMENTS
Does this pharmacy have a Telepharmacy endorsement?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1302(4)	*List the parent pharmacies and license numbers.*
Does the current staffing ratio at the Parent and the Telepharmacy sites meet the requirements?	☐ YES ☐ NO ☑ N/A	ARM 24.174.711	*Describe the typical staffing levels.*
Are the Telepharmacy prescription requirements met?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.1302(4)	
Are the required monthly visitation documents available?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.1302(4)	
Is the remote Telepharmacy site registered with the DEA?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1301.11	*Expiration Date:*
Are the DEA form requirements for Telepharmacy met?	☐ YES ☐ NO ☑ N/A	21 CFR 1305.12	

Are the DEA Registration/Requirements for Telepharmacy met?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1302(4)	
Are technician requirements for Telepharmacy met?	☐ YES ☐ NO ☑ N/A	ARM 24.174.1302(4)	
Are the communication systems in place for Telepharmacy?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.1302(4)	*Describe the current communication system.*
Is the staff offering counseling at the remote Telepharmacy site?	☐ YES ☐ NO ☐ NEEDS IMPROVEMENT ☑ N/A	ARM 24.174.1302(4)	

State of Montana
Employment Standards Division
Board of Pharmacy

This certificate verifies licensure as:
COMMUNITY PHARMACY
Person In Charge: JASMINE LEE OLSON
With endorsements of:
TECHNICIAN UTILIZATION PLAN

PHA-PHR-LIC-103076

Status: **Active**
Expires: **11/30/2024**

OSRX INC #2675
2675 PALMER ST STE D
MISSOULA, MT 59808

Montana Department of
LABOR & INDUSTRY
RENEW OR VERIFY YOUR LICENSE AT:
https://ebiz.mt.gov/pol

Renew online at https://ebiz.mt.gov/pol by signing in with your username and password.

The renewal cycle opens 60 days prior to the expiration date on your current license.
Renew your license prior to your expiration date to avoid being charged a late fee(s).

Remember to maintain your online account information with a password, security question and a valid email address. You can update your account information by accessing the 'Account Management' link when logged in.

Montana Department of LABOR & INDUSTRY

Board of Pharmacy

05/13/2024

ATTN: JASMINE OLSON
JASMINE OLSON
1120 KENSINGTON AVE. SUITE E
MISSOULA, MT 59801

I do certify that a standard search of available records of the office of the Montana Board of Pharmacy is considered the primary source and indicates the following:

Licensee Name:	OSRX INC #2675		
Mailing Address:	2675 PALMER ST STE D MISSOULA, MT 59808		
License Number:	PHA-PHR-LIC-103076	**License Type:**	COMMUNITY PHARMACY
Original License Date:	05/02/2024	**Expiration Date:**	11/30/2024
License Status:	Active	**Licensure Method:**	

Endorsement Information:

Endorsement Type	Start Date	End Date
Technician Utilization Plan	11/20/2023	

Actions:

Our records show no adverse information concerning this licensee.

This verification is accurate for all disciplinary actions occurring after July 1, 1996. We cannot guarantee the accuracy of disciplinary actions prior to this date. However, every reasonable effort has been made to provide complete and accurate information. For information about related rules and regulations, go to http://www.pharmacy.mt.gov .

Acting on behalf of the Montana Board of Pharmacy.

Deputy Division Administrator

Signature Title

Montana Department of Labor & Industry
Business Standards Division
301 S. Park Avenue
PO Box 200513
Helena, MT 59620
(406) 444-6880
DLIBSDHelp@mt.gov

List of officers and directors

OSRX, Inc.

1120 Kensington Ave. Suite E

Missoula, MT. 59801

FEIN: 83-0669663

Name	Title
Amy Frost	Owner, Vice-President, CPO
Anthony Sampietro	Owner, President, CEO
Eric Garner	Chief Commercial Officer
Brian Holdorf	Chief Formulation Officer
Frank Allen	Director of Operations

OSRX, Inc. Ownership Structure

OSRX, Inc.

1120 Kensington Avenue Suite E

Missoula MT 59801

FEIN 83-0669663

Effective Date of ownership change 04/01/2019.

Date of Incorporation in DE 04/27/2018 File #6862461

info@osrxpharmaceuticals.com

Ph:406-541-6121

Fax: 406-541-6267

Owner/President

Anthony Sampietro 60%

[redacted]th Street

Hermosa Beach, CA 90254

[redacted]

Owner/Vice President

Amy Frost Pharm.D 40%

[redacted]Roman Drive

Stevensville, MT 59870

[redacted]

OSRX, Inc. - Cap Table - Stakeholder Details Report with Voting Rights (report run on 08-Sep-2023 for							
Employee Number	Last Name	First Name	COMMON STOCK	Total Outstanding	Percent of Total	Fully Diluted	Percent of Fully
SAMPIETRO A	Sampietro	Anthony	48,000	48,000	60.00%	48,000	60.00%
FROST A	Frost	Amy	32,000	32,000	40.00%	32,000	40.00%
			80,000	**80,000**	**100.00%**	**80,000**	**100.00%**

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler OSRX, Inc. #2675

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2675 Palmer Street Suite D

City Missoula State MT Zip 59808

Mailing Address (if different from physical address) 1120 Kensington Ave. Suite E

City Missoula State MT Zip 59801

Telephone 406-541-6121 Website www.osrxpharmaceuticals.com

Licensing Company Email info@osrxpharmaceuticals.com

Section 2: Personal Information

First Jasmine Middle Lee Last Olson

Alias(es, nicknames, name changes, etc.) Maiden name: Jasmine Lee Meuchel

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Kelly Island Ct.

City Missoula State MT Zip 59808

Telephone [redacted] Email info@osrxpharmaceuticals.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Montana & U of M Skaggs School of Pharmacy			09/95-12/01	
Address		City	State	Zip
341 Skaggs Building		Missoula	MT	59812
Diploma/Degree obtained, if any				
PharmD				

School Name			From - To (MM/YY – MM/YY)	
Big Sky High School			09/91-09/95	
Address		City	State	Zip
3100 Suoth Ave W		Missoula	MT	59804
Diploma/Degree obtained, if any				
High School				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/15-present	[redacted]Kelly Island Ct.	Missoula	MT	59808
04/04-06/15	[redacted] N 102nd Pl.	Scottsdale	AZ	85255
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
OSRX, Inc.			09/21 - present
Business Address	**City**	**State**	**Zip**
1120 Kensington Ave. Suite E	Missoula	MT	59801
Phone	**Title**		**Number of Employed Hours**
406-541-6121	Pharmacist, Director of Pharmacy		6,000

Description of Duties

Processing prescriptions, patient counseling, recordkeeping, dur review, regulatory management, inspections, employee management, sop development and training of employees.

Business Name			From - To (MM/YY – MM/YY)
Wal Mart			06/15-09/21
Business Address	**City**	**State**	**Zip**
702 SW 8th St.	Bentonville	AR	72716
Phone	**Title**		**Number of Employed Hours**
479-273-8866	Pharmacist		8,000

Description of Duties

Processing and verifying prescriptions, patient counseling, mtm services, immunizations and point of care testing, recordkeeping, inspections.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Jasmine Lee Olson, **certify that as the designated representative for**

OSRX, Inc. #2675,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JO I am at least 21 years of age;
3. JO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jasmine Olson

Print Name (First, Last)

Jasmine Olson

Original Signature (electronic, copies or stamps not accepted)

May 28, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jasmine Olson

Print Name (First, Last)

Jasmine Olson

Original Signature (electronic, copies or stamps not accepted)

May 28, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of MONTANA, ss. County of MISSOULA

I, Jasmine Olson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jasmine Olson

Original Signature

May 28, 2024

Date

Subscribed and Sworn to before me this 28 day of MAY, 2024.

Notary Public Signature

PAYDN EVANS NOTARIAL SEAL STATE OF MONTANA

PAYDN EVANS
NOTARY PUBLIC for the State of Montana
Residing at Missoula, MT
My Commission Expires February 11, 2026.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site OSRX, Inc. #2675

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 2675 Palmer Street Suite D

City Missoula State MT Zip 59808

Mailing Address (if different from physical address) 1120 Kensington Ave. Suite E

City Missoula State MT Zip 59801

Telephone 406-541-6121 Website www.osrxpharmaceuticals.com

Licensing Company Email info@osrxpharmaceuticals.com

Section 2: Personal Information

First Amy Middle Ann Last Frost

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Addres [redacted]Roman Drive

City Stevensville State MT Zip 59870

Telephone [redacted] Email info@osrxpharmaceuticals.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Montana School of Pharmacy		08/01-05/05	
Address	City	State	Zip
341 Skaggs Building	Missoula	MT	59812
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			
School Name		From - To (MM/YY – MM/YY)	
Montana State University		09/96-05/00	
Address	City	State	Zip
100 College Street	Bozeman	MT	59718
Diploma/Degree obtained, if any			
Bachelors of Science-Microbiology			
School Name		From - To (MM/YY – MM/YY)	
Darby High School		08/92-06/96	
Address	City	State	Zip
209 School Dr	Darby	MT	59829
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/02-present	[redacted]Roman Drive	Stevensville	MT	59870
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
OSRX, Inc.			05/19-present
Business Address	**City**	**State**	**Zip**
1120 Kensington Ave Suite E	Missoula	MT	59801
Phone	**Title**		
406-541-6121	Partner, Owner, PIC		
Description of Duties			
Regulatory and Operations management			

Business Name			From - To (MM/YY – MM/YY)
Pinnacle Compounding, LLP.			
Business Address	**City**	**State**	**Zip**
1120 Kensington Ave Suite E	Missoula	MT	59801
Phone	**Title**		
406-541-6121	Partner, Owner, PIC		
Description of Duties			
Regulatory and Operations management			

Business Name			From - To (MM/YY – MM/YY)
Pinnacle Compounding, LLC			08/13-11/16
Business Address	**City**	**State**	**Zip**
1120 Kensington Ave Ste E	Missoula	MT	59801
Phone	**Title**		
406-541-6121	PIC		
Description of Duties			
Operation and management of pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Rivers Edge Pharmacy DBA Ridgeway Pharmacy			2007-01/12
Business Address	**City**	**State**	**Zip**
39 Stevi Cutoff Rd W	Stevensville	MT	59870
Phone	**Title**		
406-777-4410	Owner, PIC		
Description of Duties			
Operation and management of pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2013-2023	N/A	See below	See explanation below	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		State Boards of Pharmacy		
Reason/Charge				
Pharmacy of Pharmacist Licensure, Board Meeting Attendance				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Applicant, Attendee		N/A		
Name of Business/Industry/Entity				
Pinnacle Compounding, OSRX, Inc, Amy Frost, RPh				

Provide explanation below:

Certain State Boards require an in person appearance for license approval of either a new pharmacy application or individual pharmacist license. The appearance before these Boards was not related to discipline or violations. Each appearance was part of the routine application process in the corresponding state and resulted in an approved license. these states include; Nevada, South Carolina, North Carolina, Arkansas, Alabama.

Attendance of Board meetings and appearance to offer public comment regarding proposed regulation changes, Montana.

Amy Frost
Original Signature (electronic, copies or stamps not accepted)

5/28/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amy Frost

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/28/24

Date

Please have this section completed in the presence of a Notary Public.

State of MONTANA, ss. County of MISSOULA

I, Amy Frost, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/28/24

Date

Subscribed and Sworn to before me this 28 day of MAY, 2024.

Notary Public Signature

PAYDN EVANS
NOTARY PUBLIC for the
State of Montana
Residing at Missoula, MT
My Commission Expires
February 11, 2026.

PAYDN EVANS NOTARIAL SEAL STATE OF MONTANA

(Seal)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # ___4___. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/14/2021	7/29/2022	MA		Suffolk
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2841cv00886		Suffolk Superior Court		
Reason/Charge				
See below				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Plaintiffs: Drake Partners Equity, LLC; Drake Pinnacle LLC; and Drake Capital LLC		Civil Lawsuit		
Name of Business/Industry/Entity				
Ocular Science, Inc.				

Provide explanation below:

Drake Partners Equity, LLC, Drake Pinnacle LLC, and Drake Capital LLC (collectively "Drake") filed a civil lawsuit in Suffolk Superior Court against Ocular Science and its President and CEO, Anthony Sampietro (collectively, "Ocular"), for, among other things, Breach of Fiduciary Duty, Conversion, violation of 93A, Breach of Merger Agreements, Breach of Warrant Agreement, and Breach of a Credit Agreement. Drake also sued Ocular's lawyers, Wilson Sonsini Goodrich & Rosati, LP. Ocular denied (and continues to deny) all wrongdoing. The parties have now settled the matter, and the lawsuits have been dismissed.

Original Signature (electronic, copies or stamps not accepted)

5/28/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amy Frost

Print Name (First, Last)

Amy Frost

Original Signature (electronic, copies or stamps not accepted)

5/28/24

Date

Please have this section completed in the presence of a Notary Public.

State of MONTANA, ss. County of MISSOULA

I, Amy Frost, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Amy Frost

Original Signature

5/28/24

Date

Subscribed and Sworn to before me this 28 day of MAY, 2024.

Notary Public Signature

PAYDN EVANS NOTARIAL SEAL STATE OF MONTANA

PAYDN EVANS
NOTARY PUBLIC for the
State of Montana
Residing at Missoula, MT
My Commission Expires
February 11, 2026.

(Seal)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
July 14, 2020	July 19, 2023	MT	Missoula	Missoula
Case # DV-21-61		**Governing, licensing, Arresting Presiding Body/Agency/Court** Montana Fourth Judicial District Court		
Reason/Charge Marital Status Discrimination				
Plaintiff/Defendant/Claimant/Respondent Jennifer Baker			**Lawsuit/Arbitration/Bankruptcy** Baker v. OSRX, Inc., DV-21-61	
Name of Business/Industry/Entity OSRX, Inc.				

Provide explanation below:

I am a shareholder and officer of OSRX, Inc. OSRX, Inc. employed Jennifer Baker as a part-time intern while she was in college, but discontinued her employment in January of 2020, at the outset of the Covid-19 pandemic. Around the same time, OSRX also terminated a vendor contract with Ms. Baker's husband's company. Ms. Baker asserted that her employment termination violated Montana's unique employment laws, namely Montana's statutory wrongful discharge act and Montana's marital status discrimination statute.

On July 14, 2020, Ms. Baker filed her claim with the Montana Human Rights Bureau, which found "no reasonable cause to believe discrimination or retaliation occurred." Ms. Baker appealed that decision to the Montana Human Rights Commission, which affirmed that decision and dismissed her case. Ms. Baker then appealed those decisions to Montana District Court. Ms. Baker was awarded a nominal sum, following a jury trial. The matter ultimately settled in July of 2023 for a confidential amount, pending OSRX's appeal.

Original Signature (electronic, copies or stamps not accepted)

5/28/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amy Frost

Print Name (First, Last)

Amy Frost

Original Signature (electronic, copies or stamps not accepted)

5/28/24

Date

Please have this section completed in the presence of a Notary Public.

State of MONTANA, ss. County of MISSOULA

I, Amy Frost, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Amy Frost

Original Signature

5/28/24

Date

Subscribed and Sworn to before me this 28 day of MAY, 2024.

Notary Public Signature

PAYDN EVANS NOTARIAL SEAL STATE OF MONTANA

PAYDN EVANS
NOTARY PUBLIC for the
State of Montana
Residing at Missoula, MT
My Commission Expires
February 11, 2026 (Seal)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
July 20,2021		CA	San Diego	Orange
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Case No. 21-cv-01305-BAS		Southern District of California,		
Reason/Charge				
False advertising, trademark infringement, false designation of origin, common law unfair competition, violation of California's UCL, and copyright infringement.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Defendant		Lawsuit		
Name of Business/Industry/Entity				
OSRX, Inc.				

Provide explanation below:

ImprimisRx, Inc. v. OSRX, Inc., et al., Case No. 21-cv-01305-BAS (S.D. Cal). On July 20, 2021, ImprimisRx, LLC ("ImprimisRX") filed a lawsuit against OSRX, Inc. and Ocular Science, Inc. (collectively, "Ocular") in the Southern District of California, alleging claims for false advertising, trademark infringement, false designation of origin, common law unfair competition, violation of California's UCL, and copyright infringement. ImprimisRx amended its complaint with respect to the false advertising claims, ImprimisRx asserted that Ocular made false statements regarding its compliance with Section 503A of the FDCA, the safety and efficacy of its products, and whether its products are intended to treat certain maladies. ImprimisRx's trademark claims are based on Ocular's naming convention for its ophthalmic formulations, using abbreviated forms of the active ingredients (TIM-LAT, TIM-BRIM-DOR, TIM-BRIM-DOR-LAT, PRED-BROM, MOXI-BROM, PRED-KETOR, PRED-GATI-BROM, PRED-MOXI-BROM, PRED-MOXI, DEX-MOXI), which ImprimisRx claims as protected trademarks. ImprimisRx's copyright claims are based on Ocular's purportedly infringing use of a printed order form. Ocular denied ImprimisRx's claims and brought counterclaims seeking to invalidate ImprimisRx's claimed trademarks at issue and alleging false advertising against ImprimisRx.

On June 2, 2023, Ocular filed a motion for summary judgment with respect to ImprimisRx's false advertising claims. The Court granted Ocular's motion on December 12, 2023, finding that ImprimisRx offered "no evidence it was actually injured by [Ocular's] alleged misstatements." The Court also granted ImprimisRx's motion for summary judgment and dismissed Ocular's false advertising counterclaims. Throughout this lawsuit, ImprimisRx's central focus was its false advertising claim based on Ocular's compliance with Section 503A. Thus, following summary judgment, the core claim in this lawsuit has been resolved (pending potential appeals), and Ocular believes that it has significant defenses to ImprimisRx's remaining claims.

Original Signature (electronic, copies or stamps not accepted)

5/28/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amy Frost

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/28/24

Date

Please have this section completed in the presence of a Notary Public.

State of MONTANA, ss. County of MISSOULA

I, Amy Frost, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/28/24

Date

Subscribed and Sworn to before me this 28 day of MAY, 2024.

Notary Public Signature

PAYDN EVANS NOTARIAL SEAL STATE OF MONTANA

PAYDN EVANS
NOTARY PUBLIC for the State of Montana
Residing at Missoula, MT
My Commission Expires February 11, 2026.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site OSRX, Inc. #2675

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 2675 Palmer Street Suite D

City Missoula State MT Zip 59808

Mailing Address (if different from physical address) 1120 Kensington Ave Suite E

City Missoula State MT Zip 59801

Telephone 406-541-6121 Website info@osrxpharmaceuticals.com

Licensing Company Email _____

Section 2: Personal Information

First Anthony Middle _____ Last Sampietro

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] 4th Street

City Hermosa Beach State CA Zip 90254

Telephone [redacted] Email info@osrxpharmaceuticals.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Connecticut		09/87-05/92	
Address	**City**	**State**	**Zip**
352 Mansfield Rd	Storrs	CT	06269
Diploma/Degree obtained, if any			
Bachelor Science Marketing			

School Name		From - To (MM/YY – MM/YY)	
Foran High School		09/83-06/87	
Address	**City**	**State**	**Zip**
80 Foran Rd.	Millford	CT	06460
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/13-present	[redacted]4th Street	Hermosa Beach	CA	90254
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: OSRX, Inc.			From - To (MM/YY – MM/YY): 02/15-present
Business Address: 1120 Kensington Ave Suite E	City: Missoula	State: MT	Zip: 59801
Phone: 406-541-6121	Title: CEO, Owner, President		
Description of Duties: CEO			

Business Name: Opti Medica Corporation			From - To (MM/YY – MM/YY): 01/12-12/14
Business Address: 1310 Moffett Park Dr.	City: Sunnyvale	State: CA	Zip: 94089
Phone: 408-850-8600	Title: Director of Sales		
Description of Duties: Director of Sales			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # ___4___. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/14/2021	7/29/2022	MA		Suffolk
Case # 2841cv00886		**Governing, licensing, Arresting Presiding Body/Agency/Court** Suffolk Superior Court		
Reason/Charge See below				
Plaintiff/Defendant/Claimant/Respondent Plaintiffs: Drake Partners Equity, LLC; Drake Pinnacle LLC; and Drake Capital LLC			**Lawsuit/Arbitration/Bankruptcy** Civil Lawsuit	
Name of Business/Industry/Entity Ocular Science, Inc.				

Provide explanation below:

Drake Partners Equity, LLC, Drake Pinnacle LLC, and Drake Capital LLC (collectively "Drake") filed a civil lawsuit in Suffolk Superior Court against Ocular Science and its President and CEO, Anthony Sampietro (collectively, "Ocular"), for, among other things, Breach of Fiduciary Duty, Conversion, violation of 93A, Breach of Merger Agreements, Breach of Warrant Agreement, and Breach of a Credit Agreement. Drake also sued Ocular's lawyers, Wilson Sonsini Goodrich & Rosati, LP. Ocular denied (and continues to deny) all wrongdoing. The parties have now settled the matter, and the lawsuits have been dismissed.

Original Signature (electronic, copies or stamps not accepted)

5/23/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anthony Sampietro

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/23/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/23/24

Date

Please see attached California Jurat

Subscribed and Sworn to before me this _____ day of _____.

_____

Notary Public Signature

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 23rd day of May, 2024,
Date *Month* *Year*
by
(1) Anthony Sampietro
(and (2)_____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ROBIN J. FOSSELMAN
Notary Public - California
Los Angeles County
Commission # 2410413
My Comm. Expires Aug 3, 2026

Signature Robin J Fosselman
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document
Title or Type of Document: Personal History Application Document Date: _____
Number of Pages: _____ Signer(s) Other Than Named Above: _____

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Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
July 14, 2020	July 19, 2023	MT	Missoula	Missoula

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DV-21-61	Montana Fourth Judicial District Court

Reason/Charge
Marital Status Discrimination

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Jennifer Baker	Baker v. OSRX, Inc., DV-21-61

Name of Business/Industry/Entity
OSRX, Inc.

Provide explanation below:

I am a shareholder and officer of OSRX, Inc. OSRX, Inc. employed Jennifer Baker as a part-time intern while she was in college, but discontinued her employment in January of 2020, at the outset of the Covid-19 pandemic. Around the same time, OSRX also terminated a vendor contract with Ms. Baker's husband's company. Ms. Baker asserted that her employment termination violated Montana's unique employment laws, namely Montana's statutory wrongful discharge act and Montana's marital status discrimination statute.

On July 14, 2020, Ms. Baker filed her claim with the Montana Human Rights Bureau, which found "no reasonable cause to believe discrimination or retaliation occurred." Ms. Baker appealed that decision to the Montana Human Rights Commission, which affirmed that decision and dismissed her case. Ms. Baker then appealed those decisions to Montana District Court. Ms. Baker was awarded a nominal sum, following a jury trial. The matter ultimately settled in July of 2023 for a confidential amount, pending OSRX's appeal.



Original Signature (electronic, copies or stamps not accepted)

5/20/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anthony Sampietro

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 5/20/21

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 5/20/21

Please see attached California Acknowledgment

Subscribed and Sworn to before me this _____ day of _____.

_____

Notary Public Signature

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

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☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

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State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 23rd day of May, 2024,
Date *Month* *Year*
by
(1) Anthony Sampietro
(and (2)_____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ROBIN J. FOSSELMAN
Notary Public - California
Los Angeles County
Commission # 2410413
My Comm. Expires Aug 3, 2026

Signature Robin J. Fosselman
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

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Description of Attached Document
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This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
July 20,2021		CA	San Diego	Orange
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Case No. 21-cv-01305-BAS		Southern District of California,		
Reason/Charge				
False advertising, trademark infringement, false designation of origin, common law unfair competition, violation of California's UCL, and copyright infringement.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Defendant		Lawsuit		
Name of Business/Industry/Entity				
OSRX, Inc.				

Provide explanation below:

ImprimisRx, Inc. v. OSRX, Inc., et al., Case No. 21-cv-01305-BAS (S.D. Cal). On July 20, 2021, ImprimisRx, LLC ("ImprimisRX") filed a lawsuit against OSRX, Inc. and Ocular Science, Inc. (collectively, "Ocular") in the Southern District of California, alleging claims for false advertising, trademark infringement, false designation of origin, common law unfair competition, violation of California's UCL, and copyright infringement. ImprimisRx amended its complaint with respect to the false advertising claims, ImprimisRx asserted that Ocular made false statements regarding its compliance with Section 503A of the FDCA, the safety and efficacy of its products, and whether its products are intended to treat certain maladies. ImprimisRx's trademark claims are based on Ocular's naming convention for its ophthalmic formulations, using abbreviated forms of the active ingredients (TIM-LAT, TIM-BRIM-DOR, TIM-BRIM-DOR-LAT, PRED-BROM, MOXI-BROM, PRED-KETOR, PRED-GATI-BROM, PRED-MOXI-BROM, PRED-MOXI, DEX-MOXI), which ImprimisRx claims as protected trademarks. ImprimisRx's copyright claims are based on Ocular's purportedly infringing use of a printed order form. Ocular denied ImprimisRx's claims and brought counterclaims seeking to invalidate ImprimisRx's claimed trademarks at issue and alleging false advertising against ImprimisRx.

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Original Signature (electronic, copies or stamps not accepted)

5/20/24
Date

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Anthony Sampietro

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/23/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/23/24

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

Signature of Document Signer No. 1

Signature of Document Signer No. 2 (if any)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 23rd day of May, 2024,
Date *Month* *Year*
by
(1) Anthony Sampietro
(and (2)_____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ROBIN J. FOSSELMAN
Notary Public - California
Los Angeles County
Commission # 2410413
My Comm. Expires Aug 3, 2026

Signature Robin J. Fosselman
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document
Title or Type of Document: Statement of Responsibility **Document Date:** _____
Number of Pages: _____ **Signer(s) Other Than Named Above:** _____

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11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FB3527857 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Belmar Pharmacy Florida, LLC d/b/a/ Belmar Pharmacy

Physical Address: 2500 Lakepointe Parkway

City: Odessa State: FL Zip: 33556

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 877-418-4692 Toll Free # (NAC 639.708, NRS 639.23286): 877-418-4692

Fax: 877-418-4690 Contact Email: jessica.michieli@belmarpharma.com

Website: belmarpharmasolutions.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Kirk Downing

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23832

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: See attached List NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Belmar MidCo., Inc.

Corporation/Organization Name: Belmar Pharmacy Florida, LLC d/b/a Belmar Pharmacy

Mailing Address: 2500 Lakepointe Parkway

City: Odessa State: FL Zip: 33556

Telephone: 877-418-4692 Email: Jessica.Michieli@belmarpharma.com

Contact Person Name: Jessica Michieli

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist In Charge (title) for Belmar Pharmacy Florida, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Kirk Downing

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/2/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kirk Downing

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/2/24

Date

Board Use Only	Date Received: 1/10/24	Amount: $500 - check 0526

FLORIDA DEPARTMENT of STATE DIVISION OF CORPORATIONS

Sunbiz.org DIVISION of CORPORATIONS
an official State of Florida website

Detail by Entity Name

Foreign Limited Liability Company
BELMAR PHARMACY FLORIDA, LLC

Filing Information

Document Number	M22000016011
FEI/EIN Number	92-0734066
Date Filed	10/18/2022
State	DE
Status	ACTIVE
Last Event	LC STMNT OF RA/RO CHG
Event Date Filed	02/09/2023
Event Effective Date	NONE

Principal Address

7901 4th St N
STE 300
St. Petersburg, FL 33702

Changed: 02/25/2024

Mailing Address

117 S Lexington Street
STE 100
Harrisonville, MO 64701

Changed: 02/25/2024

Registered Agent Name & Address

REGISTERED AGENTS INC
7901 4th St N
STE 300
St. Petersburg, FL 33702

Name Changed: 02/09/2023

Address Changed: 02/25/2024

Authorized Person(s) Detail

Name & Address

Title Manager

Belmar Midco, Inc.
7901 4th St N STE 300
St. Petersburg, FL 33702

Annual Reports

Report Year	Filed Date
2023	02/25/2023
2024	02/25/2024

Document Images

02/25/2024 -- ANNUAL REPORT	View image in PDF format
02/25/2023 -- ANNUAL REPORT	View image in PDF format
02/09/2023 -- CORLCRACHG	View image in PDF format
10/18/2022 -- Foreign Limited	View image in PDF format

Ownership Information for Belmar Pharmacy Florida, LLC.

Belmar Pharmacy Florida, LLC. D/B/A Belmar Pharmacy
2500 Lakepointe Parkway
Odessa, FL 33556

Officers of Belmar Pharmacy Florida, LLC.:

- Robert J. Kilgore, CEO and President
  [redacted]iolet Street, Suite 140
  Golden, CO 80401
  [redacted]

- David P. Malm, Secretary and Treasurer
  [redacted]Boylston Street, # 9009
  Boston, MA 02116
  [redacted]

Belmar Pharmacy Florida, LLC is wholly owned by Belmar MidCo, Inc.

Belmar MidCo, Inc.
231 Violet St., Ste 100
Golden, CO 80401
(720) 531-5364

Officers and Directors of Belmar MidCo, Inc.:

- Robert Kilgore, CEO and President
- David P. Malm, Secretary, Treasurer and Director

Belmar Midco, Inc. is wholly owned by Belmar Holdings, Inc.:

Belmar Holdings, Inc.
c/o Webster Equity Partners
1000 Winter Street
Waltham, MA 02451
Attn: David Malm

Officers and Directors of Belmar Holdings, Inc.:

- Robert Kilgore, CEO and President
- David P. Malm, Secretary, Treasurer and Director
- W. Brandon Ingersoll, Director
- Doug Williams, Director
- David W. Hill, Director
- Dr. Angela DeRosa, Director
- Matt Beer, Director

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV355 - Community Pharmacy (New Business / Change of Owner)

File # 29265
Insp # 191925

NAME	PERMIT NUMBER	DATE OF INSPECTION
Belmar Pharmacy Florida, LLC		06/27/2023
DOING BUSINESS AS BELMAR PHARMACY		
STREET ADDRESS 2500 Lakepointe Parkway	**TELEPHONE #** 877-418-4692	**EXT**
CITY ODESSA	**COUNTY** HILLSBOROUGH	**STATE/ZIP** FL/33556

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30am-5:00pm
Monday Y	Monday Hours 8:30am-5:00pm
Tuesday Y	Tuesday Hours 8:30am-5:00pm
Wednesday Y	Wednesday Hours 8:30am-5:00pm
Thursday Y	Thursday Hours 8:30am-5:00pm
Friday Y	Friday Hours 8:30am-5:00pm
Saturday Y	Saturday Hours 8:00am-12:00pm
Sunday N	Sunday Hours Closed

Registered Pharmacist / Intern / Tech

License # PS47195	Licensee Name Perry Katsamakis, PDM
License Type Registered Pharmacists	
License # PS51092	Licensee Name Zubair Zafrullah
License Type Registered Pharmacists	
License # RPT72339	Licensee Name Savannah Wells
License Type Pharmacy Tech	
License # PS62849	Licensee Name Ryan Vince
License Type Registered Pharmacists	
License # RPT7588	Licensee Name Amy Marie O'Brien
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # pending	

License Relations

Pharmacy Affiliate

KATSAMAKIS, PERRY	License # 47195

RX DPT MGR/COR/POR

KATSAMAKIS, PERRY	License # 47195

Special Sterile Compounding

BELMAR PHARMACY FLORIDA, LLC	License #

Rx Department is open for a minimum of 20 hours per week and signage stating the hours the pharmacy department is open. [64B16-28.1081, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-28.1035, F.A.C]	Yes
Private Consultation Area available. [64B16-28.1035, F.A.C]	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes
Prescription department is clean and safe, has a sink with running water convenient to the prescription department, and references and equipment necessary for the practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy has a designated Prescription Department manager with a current and active Florida license. [465.018, F.S.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16 -27.410(2)(a) F.A.C.] *See Pharmacist and Technician Ratios SOP 2.00.05*	Yes
Continuous Quality Improvement Program described in Policy and Procedure manual [64B16-27.300 F.A.C.] [766.101(1)(a)(l) F.S.] *Reviewed SOP 11.0.07 Supplier Qualification "Quality Assurance/Quality Control" and SOP 11.00.25 "Quality Program"*	Yes
Policy and Procedure to prevent the fraudulent dispensing or controlled substances. [465.022 (4) F.S] *Reviewed SOP 14.00.07 "Evaluating the Legitimacy of CS prescriptions"-speaks to registration with PDMP*	Yes
Prescription Department is securable from unauthorized access. [64B16-28.109 F.A.C.] *Badge access to designated location*	Yes
All medications to be purchased from a Florida licensed wholesaler [499-F.S.] *Proposed wholesalers: McKesson, Medisca, Fagron, Letco, Pharma Solutions* *Reviewed SOP 11.0.07 "Supplier Qualification and Audit" for API qualification*	Yes
The following rules have been reviewed with the applicant: 64B16-30.003, F.A.C. (Citations), 64B16-28.140(4) F.A.C. (Compounding Records), 64B16-28.1081, F.A.C. (Regulation of Daily Operating Hours; Commencement of Operation-s), 64B16-28.202, F.A.C (Closing of a Pharmacy)	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent. *SOP 4.00.08 "Pharmacy Practice"*	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Remarks:

Pharmacy intends to procure licensure in several states. Pharmacy will perform non-sterile and sterile compounding for human use. Computer system Life File (for dispensing) will be in place pending licensure and PK for compounding.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CULLIPHER, MALA

Date:6/27/2023

Representative:

Perry Katsamakis

Date:6/27/2023

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 29055
Insp # 192920

NAME	PERMIT NUMBER	DATE OF INSPECTION
Belmar Pharmacy Florida, LLC		07/20/2023
DOING BUSINESS AS		
BELMAR PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
2500 Lakepointe Parkway		
CITY	**COUNTY**	**STATE/ZIP**
ODESSA	HILLSBOROUGH	FL/33556

Additional Information

Business Operation Hours

M-T-W-TH-F N	Monday Y
Monday Hours 8:30am-5:00pm	Tuesday Y
Tuesday Hours 8:30am-5:00pm	Wednesday Y
Wednesday Hours 8:30am-5:00pm	Thursday Y
Thursday Hours 8:30am-5:00pm	Friday Y
Friday Hours 8:30am-5:00pm	Saturday Y
Saturday Hours 8:00am-12:00pm	Sunday N
Weekly Hours 8:30 am - 5:00 pm	Sunday Hours Closed

Registered Pharmacist / Intern / Tech

License # PS47195	Licensee Name Perry Katsamakis, PDM
License Type Registered Pharmacists	
License # RPT72339	Licensee Name Savannah Wells
License Type Pharmacy Tech	
License # PS62849	Licensee Name Ryan Vince
License Type Registered Pharmacists	
License # RPT7588	Licensee Name Amy Marie O'brien
License Type Pharmacy Tech	
License # PS51092	Licensee Name Zubair Ullah Zafrullah
License Type Registered Pharmacists	
License # RPT85138	Licensee Name Joyce Torres
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # pending	

License Relations

RX DPT MGR/COR/POR

KATSAMAKIS, PERRY	License # 47195

Special Sterile Compounding

BELMAR PHARMACY FLORIDA, LLC	License # 34652

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	N/A
5. Medium Risk CSP's, in absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	N/A

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas] *Air Clean systems weighing balances noted in non-HD and HD prep room.*	Yes
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *No product at this time, until wholesaler contracts are set up*	Yes
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *Firm will only prepare batches*	N/A
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *Proposed filters -MDI Asepticap PES MDI*	Yes
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *Per SOP 7.00.06 "Sterilization via Filtration"*	N/A
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *Pharmacy plans on using appropriate MDI filters*	N/A
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam] *Will be used to steam sterilize utensils, stoppers, tweezers, spin bars, reusable weighing spatulas but not to terminelly sterilize solutions.* *Plan is to use BI's EZ test in autoclave Mesa labs (order has been placed).* *3 Autoclaves: Tuttnauer SN 21010108, 21080235, 21080239* *Per SOP 15.00.09 "Use, Verification and Maintenance of the Autoclave (Steam Heat Sterilization by the Autoclave)", items to be sterilized by Tuttenauer*	N/A
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat] *3 Despatch ovens SN : 2000863, 199614, 199615* *BI's will be Mesa labs dry amps* *Ovens are located in HD washroom and non-HD washroom-ovens are pass-throughs to sterile glass -will be stored in ISO 7 post depyrogenation*	N/A
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat] *Not currently compounding*	N/A
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat] *Load patterns still need to be established-please ensure this is done prior to the initiation of compounding, however SOP 15.00.18 "Equipment" see 6.1 which allows for disposable sterile items to be used in compounding.* *Inspector was provided a work order for validation of all 3 dry heat ovens-to be completed by September and will include temperature mapping-per SOP "Equipment" 15.00.18*	Yes
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *No product yet-until licensure*	N/A

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>] *Plan is to use Pharmetric rapid test*	N/A
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] *Reviewed SOP 7.00.07 "Finished Sterile Preparation Verification and Final Release"-see table*	N/A
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] *TBD*	N/A
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test] *Not currently compounding*	N/A

21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS] *Noted Quarantine room 138*	N/A

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing] *per SOP 7.00.07*	N/A
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>] *Not currently compounding, pharmacy will not be compounding intrathecal medication.*	N/A
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing] *per SOP "Finished Sterile Preparation Verification and Release" 7.00.07*	N/A

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs] *Reviewed Antec on Delta Controls trend log*	Yes
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs] *Per MTA report dated 6/5 & 6/6 ACPH documented as 48 for HD buffer room 120C*	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs] *All BSC's are externally vented*	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	N/A

44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs] *Facility provided Mckesson Perry powder free sterile gloves rated to handle HD's*	Yes
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs] *Sterile HD Buffer room has 4 Nuaire BSC's and 3 Nuaire BSC's in Prep room for weighing HD powders*	N/A
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs] *Plan :#120 HD chemical storage distinguishing it from #127 non-HD chemo storage-will be observed at next walk through*	Yes
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs] *per Critical Point modules*	Yes
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs] *resides with HR*	Yes
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs] *Account needs to be set up with Steri Cycle- black containers to be installed prior to initiating compounding*	N/A

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *June 5, June 6, 2023 by MTA* *Positive pressure Ante room (ISO 8), Prep room aka 119B (ISO 8), Buffer room 119C (ISO 7)* *PEC's: 4 x Germfree LFH (ISO 5) in 119 C* *5 Hepa filtered PT's* *Negative pressure Ante room 120A HD, (ISO 7), HD Prep room 120B (ISO 7), HD Buffer room 120 C (ISO 7)* *PEC's: 4 x Nuarie Class II A2 BSC (ISO 5)-in 120C* *4 Hepa filtered PT's in cleanroom suite* *All clean rooms have low wall vent returns and terminal ceiling hepa filters*	Yes
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *4 persons present during dynamic smoke study*	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *Reviewed Antec on Delta Controls trend log*	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *ACPH documented as 102 for non-HD buffer room (119C) from June 5, 6, 2023*	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Pharmacy has caulked where floor meets wall*	Yes

64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Smooth ceiling*	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas] *No repeater pumps in place at time of inspection*	N/A

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *VAS date performed in-house by Microbiologist using a calibrated SAS air sampler: 6/5/23, 6/7/23 and 6/8/23 has now been resampled after actionable organisms noted-Repeated on 7/7/23 after terminal cleaning on 6/30/23*	Yes
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *Facility outsources to US Microsolutions per SOP on EM 11.00.19 "Environmental Monitoring".*	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media] *Per SOP 5 pathogens of concern-have been added to SOP "Environmental Monitoring-Sampling" 11.00.19, pharmacy received results from US micro solutions for plates sent on 7/20/23 resulting in no actionable organisms. Pharmacy uses Hardy SDA with L&T plates P595.*	Yes
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *Trends maintained in an excel now documented as cfu/m3 as per SOP 11.00.19 per 7.3.1.0.*	Yes
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Pharmacy uses Hardy TSA with L&T plates P520*	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *Organisms of concern have been added to SOP 11.00.19 table 7.5 reviewed for action levels-exceeded during June 6, 9, and July 7 2023 air sampling speciation by US Micro solutions-not actionable* *Pharmacy is currently not compounding and will possibly initiate compounding in September 2023.* *Pharmacy plans on doing weekly air sampling per SOP "Quality Assurance/Quality Control" 5.4*	Yes
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Documentation from Pestle available from July 11, 2023*	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Following June 30th terminal clean, pestle documentation provided of daily clean using Peridox RTU or Decon Spore 200 (5 mins) followed by SIPA for inside PEC's and Mon-Thu using Steri Perox (10 mins) for outside PEC's and carts. Weekly sporicidal cleaning generally Fridays using either Peridox (3 mins) or Decon Spore (5 mins) followed SIPA.*	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Dedicated one to dirty side and one to clean side of each ante room and each cleanroom*	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Carts placed in front of pass-throughs with Decon spore-follows SOP 7.00.04 Aseptic Material Transfer-see process map*	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *SOP 3.00.01 Cleaning in table in section 8.4.3 the contact time for SIPA and contact time edded to Material transfer SOP as 10 seconds*	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Documented in Pestle per SOP 3.00.01 "Cleaning of Sterile Areas"*	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *7/14/23 and 6/30/23 as noted in Pestle*	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *per SOP 7.00.01 "Hand Hygiene and Garbing HD sterile areas"* *per SOP 7.00.02 "Hand Hygiene and Garbing non-HD sterile areas"*	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Pharmacy has 3 bootie butlers, in CNC hallway and non-HD ante and HD ante rooms*	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Add Purell Waterless Surgical Scrub hands free dispenser to anterooms*	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Coveralls being donned to perform high risk compounding*	N/A
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs] *Not compound commercially available injectables*	N/A
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *Pharmacy has added high risk media fill for 2 compounders -1 RPt (SW) and 1 RPh (RV)-See Media fill Form 7.00.10-01-dated 6/9/23 qty of units compounded: 6/12/23 435 x 5ml vials-uses Soybean Casein digest medium. Pharmacy has added 2 additional technicians (JT, AO) and Pharmacist (PK) on 7/5/23-HD drugs 500 x5ml vials by technicians, pharmacist completed 100 x10ml vials on 7/5/23*	Yes
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Documented in Pestle for AO and PK completed 7/5/23*	Yes
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Documentation is maintained in Pestle*	Yes
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Hardy P520 non-refrigerated plates TSA with L&T plates used to evaluate a 3 times GFT -Incubation temps documented on Excel trend* *per SOP 11.00.12 "Personnel Monitoring"* *Additionally completed on 7/5/23 for AO and PK*	Yes
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] *Will mirror APS labels -PK is running* *SOP 10.00.01 "Labeling"- Final labels for dispensing will be from Life File*	Yes

102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] *SOP reviewed 7.00.07 "Finished Sterile Preparation Verification"* *Pharmacy plans on attaching original COA from Pharmetric*	N/A
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] *SOP 11.00.05 "Visual Inspection of Sterile Products"*	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates] *After DEA permit approved, pharmacy plans on initiating sterile compounding for stability studies and time point studies*	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :] *In process -currently not compounding*	N/A
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs] *In process -currently not compounding*	N/A
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	N/A

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Reviewed SOP 3.00.01"Cleaning of the Sterile Areas" Cleaning agents are named: Peridox, Steri-Perox, SIPA and Spor-Klenz* *Contact times of cleaning agents are listed in table under Frequency and in 7.4*	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Order of cleaning is stated in 8.9 of above policy*	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] *SOP 11.00.07 "Supplier Qualification and Audit" regarding quality and purity, for calibration see SOP 15.00.12 "Baxter Repeating Pump Use Cleaning and Maintenance"*	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs] *In draft form "Assessing non-sterile and sterile compounded product integrity during storage and shipping"*	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING] *SOP reviewed 4.00.08 "Delivery SOP"*	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)] *PK has been initiated but not actively compounding*	N/A
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	

129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

LYOPHILIZATION

135. Sterile products prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
136. A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
137.The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
138. The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
139. Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
140. Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
141. Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
142. The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
143.SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
144. The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
145. Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
146. Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin.[64B16-27.797(5) F.A.C.]	
147. Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
148. In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product.[64B16-27.797(5) F.A.C.]	
149. A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
150. Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
151. Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
152. Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnal documented in the batch record. [64B16-27.797(5) F.A.C.]	
153. Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
154. Potency, radiochemical purity or applicable test to assure label claim is conducted on every batch end documented in the batch record. In lieu of potency testing, weight based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

CORRECTIVE ACTION PLAN

155. A corrective action plan is required to be submitted within 30 days for the non-compliant items listed above.	No

Remarks:

Equipment calibrations are pending for Autoclave and Dry Heat ovens, weighing scales, repeater pumps, pH meter. Inspection conducted with PDM Perry Katsamakis, Zubair Zafrullah pharmacist, Ashley Weber, QM, Amy Obrien, Compounding Technician Supervisor, Kristen Youngdahl COO, HQ.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CULLIPHER, MALA

Date:7/20/2023

Representative:

Perry Katsamakis

Date:7/20/2023

Department of Health

Belmar Pharmacy Florida, LLC Belmar Pharmacy

License Number: PH34693

Data As Of 5/13/2024

Profession	Pharmacy
License	PH34693
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2025
License Original Issue Date	08/01/2023
Address of Record	2500 Lakepointe Parkway ODESSA, FL 33556
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

Department of Health

Belmar Pharmacy Florida, LLC Belmar Pharmacy

License Number: PH34652

Data As Of 5/13/2024

Profession	Pharmacy
License	PH34652
License Status	CLEAR/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2025
License Original Issue Date	06/28/2023
Address of Record	2500 Lakepointe Parkway ODESSA, FL 33556
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Belmar Pharmacy Florida, LLC d/b/a Belmar Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): PENDING

Physical Address: 2500 Lakepointe Parkway

City: Odessa State: FL Zip: 33556

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 877-418-4690 Toll Free # (NAC 639.708, NRS 639.23286): 877-418-4692

Fax: 877-418-4690 Contact Email: Jessica.Michieli@belmarpharma.com

Website: www.belmarpharmasolutions.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Kirk Downing

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23832

Name of Person with direct knowledge of compounding procedures: Perry Katsamakis

Email of Person with direct knowledge of compounding procedures: perry.katsamakis@belmarpharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 877-418-4690

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
See Attachment 1

4. Will you be utilizing beyond use dates in excess of USP-797? ■ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
Stability testing that includes API potency, particulate matter, appearance, pH (if applicable), endotoxin, assay for preservative, container closure, and sterility at each time point and AET testing occurring at the final time point at a minimum. Time points include T0, T30, T60, T90.

6. What laboratory performs this additional testing?
Name: ARL BioPharma
Address: 840 Research Pkwy #546
City: Oklahoma City State: OK Zip: 73104
Telephone: 405-271-1144

7. What is your procedure for visual inspection of compounded sterile products?
Every vial of every batch is visually inspected by qualified quality personnel only. Must meet and acceptance criteria to move forward with release.

8. How often do you perform glove fingertip and medial fill testing?

Quarterly

9. What is your policy if an employee fails a glove fingertip or media-fill test?

If an operator fails media fill or GFS testing the will be repeated entirely. Failures must be investigated by the quality unit and may result in operator retraining or disqualification at the discretion of the quality unit and the PIC. Organisms will be identified to the species level.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

• Hand Hygiene and Garbing - Read and understand of corresponding SOPS and a Knowledge Assessment – Initial and Annually / Qualification Checklist including GFS sampling after garbing and a visual observation – Initial and Quarterly
• Cleaning - Read and understand of corresponding SOPS, Qualification Checklist including visual observations, and a Knowledge Assessment – Initially and Annually
• Aseptic Technique - Read and understand of corresponding SOPS and a Knowledge Assessment – Initial and Annually / Qualification checklist that includes Media Fill results and viable GFS and DCA sampling directly after Media Fill completion as well as visual observations of aseptic manipulations with the PECs – Initially and Quarterly
• Additional Items - Hazardous Communication Training and Potency Testing of a CSP– Initial and Annually

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Cleaners used: Peridox RTU, Sterile 70% IPA, Steri-Perox 6%.
Daily AM: PECs, powderhoods, scales, tabletops, repeater pumps, carts, passthroughs, hot plates, sinks - sIPA
Daily PM: PECs and Powderhoods Peridox RTU Followed by sIPA / Scales, tabletops, repeater pumps, carts, passthroughs, hot plates, sinks. - Steri-perox 6% follwed by sIPA
wipe.
Weekly PM: PECs, passthroughs, sinks, hot plates, floors, powderhood, carts, tabletops, scales, trash cans, repeater pumps - PeridoxRTU followed by sIPA wipe.
Monthly PM: Entire room ceiling, walls, and floors, in addition to all items cleaned during the daily/weekly cleans - PeridoxRTu followed by sIPA wipe.

12. Who performs the sterile compounding process at your facility?

Sterile compounding technicians with oversight by the compounding pharmacists.

13. Who is responsible and accountable for the sterile compounding process at your facility?

Sterile Compounding Pharmacist- Ryan Vince, RPh
Pharmacist in Charge- Perry Katsamakis, RPh

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Room temperature. Refrigerated.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Biological safety cabinets		
2. Is your BSC or CACI vented 100% to the outside?	☒ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☒ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☒ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☒ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☒ No
7. If yes, list the name of the device: N/A		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? HAZARDOUS DRUG: Observe special handling and disposal requirements. Do not flush down a toilet or pour down a drain. Check with your pharmacist if you have any questions about the best way to dispose of medications. There may be a drug take-back program in your area. If an overdose is suspected contact your local poison control center at 1-800-222-1222 or go lo the nearest emergency room.		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Hazardous communication training (Safety procedures and hazardous communication SOP), USP <800> powerpoint training, Fit testing of n95 respirators		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

See attachment 1

2. What sterilization methods are utilized at your facility?

Sterilization via filtration

3. Does your facility utilize biological indicators? ■ Yes ☐ No

4. If yes, describe how they are utilized:

Filter integrity testing by bubble point is performed on each filter used in the compounding of CSPs prior to their release. CSPs ARE NOT terminally sterilized by steam sterilization.

Items involved in the compounding process, such as beakers, spoons, stoppers, etc., undergo steam sterilization via autoclave. A biological indicator is included with each autoclave run and the BI must be placed in the coldest part of the chamber (based on temperature mapping). The BI serves as an additional challenge to the sterilization process in addition to chemical process indicators. A positive control will be placed in the incubator once daily.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Perry Katsamakis

Name of Person who Completed the Form

Pharmacist in Charge

Title

Signature (copies or stamps not accepted)

5/1/2024

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

Belmar PHARMACY Belmar PHARMA SOLUTIONS

Attachment 1

5/1/2024

List of Sterile Compounds:

- Testosterone Cyp/DHEA 200/10mg/ml
- Testosterone Cyp/Anastrozole 200/0.5mg/ml
- Testosterone Cyp/Anastrozole 200/1mg/ml
- Gonadorelin 0.2mg/ml
- Cyanocobalamin/Semaglutide 1/1mg/ml
- Methylcobalamin 10mg/ml
- Nicotinamide Adenine Dinucleotide (NAD+) 200mg/ml
- Phenylephrine 1mg/ml
- Sermorelin 2mg/ml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Belmar Pharmacy Florida, LLC DBA Belmar Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): new application

Physical Address: 2500 Lakepointe Parkway

City: Odessa State: FL Zip: 33556

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 877-418-4690 Website: www.belmarpharmasolutions.com

Licensing Company Email: jessica.michieli@belmarpharma.com

Section 2: Personal Information

First: Robert Middle: James Last: Kilgore

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Avalanche Street

City: Littleton State: CO Zip: 80125

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Michigan - Stephen M. Ross School of Business		08/1988-05/1991	
Address	City	State	Zip
701 Tappan Avenue	Ann Arbor	Michigan	48109
Diploma/Degree obtained, if any			
Master of Business Administration (Finance)			

School Name		From - To (MM/YY – MM/YY)	
University of Michigan Law School		08/1987-05/1991	
Address	City	State	Zip
625 South State Street	Ann Arbor	Michigan	48109
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
University of Michigan		09/1983-05/1987	
Address	City	State	Zip
500 South State Street	Ann Arbor	Michigan	48109
Diploma/Degree obtained, if any			
Bachelor of Economics			

School Name		From - To (MM/YY – MM/YY)	
Jenison High School		09/1981-06/1983	
Address	City	State	Zip
2140 Bauer Rd	Jenison	Michigan	49428
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY	
Forest Hills Central High School		09/1979 - 06/1981	
Address	City	State	Zip
5901 Hall St., SE	Ada	Michigan	49546
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2019-Present	[redacted]Avalanche Street	Littleton	Colorado	80125
09/2016-06/2019	[redacted]arfield Street	Denver	Colorado	80206
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Belmar Pharmacy Florida, LLC d/b/a Belmar Pharmacy			10/2022 - Present	
Business Address	**City**		**State**	**Zip**
2500 Lakepointe Parkway	Odessa		Florida	33556
Phone	**Title**			
877-418-4690	CEO and President			
Description of Duties				
Managing the company's overall business strategy and ensuring its strong growth and performance.				

Business Name			From - To (MM/YY – MM/YY)	
MedQuest Pharmacy, Inc.			05/2023 - Present	
Business Address	**City**		**State**	**Zip**
669 West 900 North	North Salt Lake		Utah	84054
Phone	**Title**			
888-222-2956	CEO and President			
Description of Duties				
Managing the company's overall business strategy and ensuring its strong growth and performance.				

Business Name			From - To (MM/YY – MM/YY)	
Custom Rx, LLC d/b/a Custom Rx Pharmacy and Wellness Concepts			09/2022 - Present	
Business Address	**City**		**State**	**Zip**
3510 North Ridge Road, Suite 900	Wichita		KS	67205
Phone	**Title**			
316-721-2626	CEO and President			
Description of Duties				
Managing the company's overall business strategy and ensuring its strong growth and performance.				

Business Name			From - To (MM/YY – MM/YY)	
Women's International Pharmacy, Inc.			03/2021-Present	
Business Address	**City**		**State**	**Zip**
2 Marsh Court	Madison		WI	53718
Phone	**Title**			
800-279-5708	CFO & Vice President (03/2021-06/2022) CEO & President (06/2022-Present)			
Description of Duties				
Managing the company's overall business strategy and ensuring its strong growth and performance.				

Business Name			From - To (MM/YY – MM/YY)	
Drug Depot, LLC d/b/a APS Pharmacy			05/2020-Present	
Business Address	**City**		**State**	**Zip**
34911 US Highway 19 North, Suite 600	Palm Harbor		Florida	34684
Phone	**Title**			
	CFO & Vice President (05/2020-06/2022) CEO & President (06/2022-Present)			
Description of Duties				
Managing the company's overall business strategy and ensuring its strong growth and performance.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
BLA Enterprises, LLC d/b/a Green Mountain Pharmaceuticals			03/2019-Present	
Business Address		City	State	Zip
12860 West Cedar Drive, Suite 201		Lakewood	Colorado	80228
Phone	Title			
303-729-2466	CFO & Vice President (03/2019-06/2022) CEO & President (06/2022-Present)			
Description of Duties				
Managing the company's overall business strategy and ensuring its strong growth and performance.				

Business Name			From - To (MM/YY – MM/YY)	
BSO, LLC d/b/a Belmar Select Outsourcing			03/2019-Present	
Business Address		City	State	Zip
12860 West Cedar Drive, Suite 211		Lakewood	Colorado	80228
Phone	Title			
303-963-5488	CFO & Vice President (03/2019-06/2022) CEO & President (06/2022-Present)			
Description of Duties				
Managing the company's overall business strategy and ensuring its strong growth and performance.				

Business Name			From - To (MM/YY – MM/YY)	
KEBD Enterprises, LLC d/b/a Belmar Pharmacy			03/2019-Present	
Business Address		City	State	Zip
231 Violet Street, Suite 140		Golden	Colorado	80401
Phone	Title			
303-763-5533	CFO & Vice President (03/2019-06/2022) CEO & President (06/2022-Present)			
Description of Duties				
Managing the company's overall business strategy and ensuring its strong growth and performance.				

Business Name			From - To (MM/YY – MM/YY)	
Absio Corporation			10/2014-12/2018	
Business Address		City	State	Zip
4600 S Syracuse Street, 9th Floor		Denver	Colorado	80237
Phone	Title			
720-836-1222	CEO			
Description of Duties				
Managing the company's overall business strategy and ensuring its strong growth and performance.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Kilgore

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/06/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Colorado, ss. County of Jefferson

I, Robert J. Kilgore, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

05/06/2024

Date

Subscribed and Sworn to before me this 6th day of May, 2024

Notary Public Signature

ELIZABETH RENEE HANSEN
Notary Public
State of Colorado
Notary ID # 20214025458
My Commission Expires 06-28-2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Belmar Pharmacy Florida, LLC d/b/a Belmar Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH34652

Physical Address 2500 Lakepointe Parkway

City Odessa State FL Zip 33556

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Perry Middle _____ Last Katsamakis

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addres[redacted]W Cleveland St.

City Tampa State FL Zip 33609

Telephon[redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. John's University		09/2002 - 05/2010	
Address	**City**	**State**	**Zip**
81-98 170th St.	Jamaica	NY	11432
Diploma/Degree obtained, if any			
Pharm.D.			

School Name		From - To (MM/YY – MM/YY)	
Roslyn High school		09/1999 - 06/2002	
Address	**City**	**State**	**Zip**
475 Round Hill Rd.	Roslyn Heights	NY	11577
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2019 - present	[redacted]W. Cleveland St	Tampa	FL	33609
10/2015 - 04/2019	[redacted]W. Tacon St	Tampa	FL	33629
10/2013 - 10/2015	[redacted]S. Harbour Island Blvd #538	Tampa	FL	33602

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Belmar Pharmacy Florida			04/2023 - present	
Business Address	**City**		**State**	**Zip**
2500 Lakepointe Pkwy	Odessa		FL	33556
Phone	**Title**		**Number of Employed Hours**	
(877) 418-4692	Pharmacist in charge		1,440	
Description of Duties				
Oversee pharmacy setup and licensing.				

Business Name			From - To (MM/YY – MM/YY)	
APS Pharmacy			04/2021 - 04/2023	
Business Address	**City**		**State**	**Zip**
34911 US Hwy 19 N STE 600	Palm Harbor		FL	34684
Phone	**Title**		**Number of Employed Hours**	
727-787-4137	Customer service pharmacist manager		4,160	
Description of Duties				
Oversaw operations in customer service, counseled patient and clinicians.				

Business Name			From - To (MM/YY – MM/YY)	
Davis Islands Pharmacy			08/2012 - 04/2021	
Business Address	**City**		**State**	**Zip**
232 E Davis Blvd	Tampa		FL	33606
Phone	**Title**		**Number of Employed Hours**	
813-254-1888	Pharmacist		18,720	
Description of Duties				
Filled prescriptions, counseled patients.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Perry Katsamakis, **certify that as the designated representative for**

Belmar Pharmacy Florida,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PK I am at least 21 years of age;
3. PK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Perry Katsamakis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/29/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Perry Katsamakis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/29/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, Perry Katsamakis, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/29/23

Date

Subscribed and Sworn to before me this 29th day of December 2023

Notary Public Signature

JEREMY BILANCIONE
Notary Public - State of Florida
Commission # HH 120509
My Comm. Expires Apr 22, 2025

(Seal)

12

12A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Geodis Logistics LLC

Physical Address: 1004 Trade Center Pkwy, Suite 100

City: Rincon State: GA Zip: 31326

Mailing Address (if different from physical address): 7101 Executive Center Dr, Suite 333

City: Brentwood State: TN Zip: 37027

Telephone: 912-346-7501 Website: www.geodis.com

Name of Designated Representative (DR): Christopher Mitchell

Licensing Company Email: licensing.cl.us@geodis.com DR Email: chris.mitchell@geodis.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Third Party Logistics

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?	✓	
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/09/2021	01/20/2022	KS	Richmond Hill	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
Case No. [redacted]	Kansas Board of Pharmacy

Reason/Charge
Shipping OTC Drugs into KS without a proper permit

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
n/a	n/a

Name of Business/Industry/Entity
Geodis Logistics LLC

Provide explanation below:

In 2018, IQVIA, which is a state licensing vendor, was hired as a state licensing vendor for Geodis Logistics LLC and oversaw initiating, renewing, and monitoring all of Geodis' state licensing needs for drug and medical device licensing.
In April of 2019, IQVIA was tasked to complete state licensing for Geodis Logistics LLC located at 1004 Trade Center Parkway, Rincon, GA 31326 for nonprescription drugs. Geodis Logistics LLC was under the impression the task had been initiated by IQVIA and therefore started shipping into KS not knowing the application had not been sent.
In 2020, KS switched from providing a Wholesaler license to third party logistics providers and moved to licensing third party logistics providers separately.
On 9/30/2021 a Nonprescription Drug Third Party Logistics Provider application for the facility located at 1004 Trade Center Parkway, Rincon, GA 31326 was mailed to the state of KS.
On the application's Non-Resident Supplemental S-350 form, Geodis truthfully answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months." The form states if the applicant answered "yes," the applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the locations they were sent in Kansas." Included with the Application, Geodis provided requested copies of shipping records for products shipped into Kansas. The records show Geodis Logistics LLC shipped into Kansas on 28 unique days during the previous 12-month period.
On December 9, 2021, the Kansas Board of Pharmacy issued Geodis Logistics LLC a Summary Order for shipping into Kansas prior to being registered as a nonprescription drug third-party logistics provider and ordered Geodis Logistics LLC to pay a fine to the Board in the amount of $780.
On December 16, 2021, the KS Summary Order was brought to the attention of Geodis Logistics LLC by IQVIA. After discussion with IQVIA, it was concluded IQVIA would cover the fee due to failure to process Geodis' Nonprescription Drug Third Party Logistics Provider application with the KS Board of Pharmacy.
On January 20, 2022, the fee/check was sent to KS Board of Pharmacy by IQVIA on behalf of Geodis Logistics LLC and the KS registration was issued.

Original Signature (electronic, copies or stamps not accepted)

11/17/2023
Date

Full Details of Disciplinary Action

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800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

December 9, 2021

Geodis Logistics LLC
Attn: Whitney Lynch, Designated Rep
1004 Trade Center Parkway
Rincon GA 31326

RE: Case No. [redacted]

Dear Ms. Lynch:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $780. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at [redacted]

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. [redacted]
Geodis Logistics, LLC	)	
	)	
Applicant	)	

SUMMARY ORDER

NOW, on this 9th day of December 2021, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Geodis Logistics LLC. ("Applicant"), for application for registration as a non-prescription drug third-party logistics provider in the state of Kansas.

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. On October 1, 2021, the Board received Applicant's application for registration as a nonprescription drug third-party logistics provider in the State of Kansas ("Applicant's Application") at the following location: 1004 Trade Center Parkway, Rincon, Georgia.

1. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months." The form directs that if the applicant answered "yes," the applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the

locations they were sent in Kansas."

2. In conjunction with Applicant's Application, Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 28 unique days during the previous 12-month period.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f)(6), the Board may take action against the application of any third-party logistics provider upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.S.A. 65-1643(d), it shall be unlawful for any person to operate as a third-party logistics provider without first obtaining a registration from the Board.

4. Applicant's act of shipping into Kansas prior to being registered as a nonprescription drug third-party logistics provider is a violation of K.S.A. 65-1643(d) and is a basis to take action against Applicant's Application pursuant to K.S.A. 65-1627(f)(6).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's Application is hereby GRANTED but Applicant is ordered to pay a fine to the Board in the amount of $780. Applicant has 30 days from the date of this order to pay the fine and the registration shall be issued upon receipt.

NOTICES

Applicant is hereby notified as follows:

1. Applicant may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Applicant, costs of the proceedings shall be charged to Applicant.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
[redacted] Jackson, Suite [redacted]
Topeka, KS 66612

IT IS SO ORDERED.

12/9/2021
Date

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 9th day of December 2021, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Geodis Logistics LLC
1004 Trade Center Pkwy
Rincon GA 31326

Kansas Board of Pharmacy Staff

Kansas Board of Pharmacy
800 SW Jackson St. Suite 1414
Topeka, Kansas 66612-1244
P:785-296-4056
F:-785-296-8420

The Kansas Board of Pharmacy certifies that it maintains the information for the credential verification function of its internal systems, as well as performing hourly updates to the information represented. Therefore, the verification information is deemed a primary source of credential verification information, as authentic as a direct inquiry to the Board.

LICENSE VERIFICATION FOR: [redacted]

GEODIS Logistics LLC
1004 Trade Center Parkway
Rincon, GA 31326

Original Date: 1/28/2022
On Probation: No
Discipline on File: Yes

LICENSES	Effective Date	Expire Date	Status
Nonprescription 3PL Provider Permit	7/1/2022	6/30/2023	Active

KANSAS STATE BOARD OF PHARMACY

By _____ Executive Secretary

This report created on: 7/20/2022

NOTES
N/A

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Dukal Corporation

Address: 2 Fleetwood Court City: Ronkonkoma State: NY Zip: 11779

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Tennessee

Parent Company (if any): Ozburn-Hessey Holding Company, LLC

Corporation/Organization Name: Geodis Logistics LLC

Mailing Address: 7101 Executive Center Dr, Suite 333

City: Brentwood State: TN Zip: 37027

Telephone: 615-401-6400 Email: licensing.cl.us@geodis.com

Contact Person Name: Mark Vane

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Geodis Logistics LLC

Facility Name

Chris Mitchell

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/17/2023

Date

Board Use Only	Date Received: 11/21/23	Amount: 1000-CK-0000356477

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Geodis**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Geodis Logistics LLC	2000004234	116937615	RELABEL; REPACK;	[redacted] INNOVATION BLVD, CLAYTON, Indiana (IN) 46118, United States (USA)	12/31/2024
Geodis Logistics LLC	2000004234	117711757	RELABEL; REPACK;	[redacted] nnovation Blvd, Clayton, Indiana (IN) 46118-9524, United States (USA)	12/31/2024
Geodis Logistics LLC	3012894471	058253044	RELABEL; REPACK;	[redacted] Trade Center Pkwy Ste 100, Rincon, Georgia (GA) 31326, United States (USA)	12/31/2024

Showing 1 to 3 of 3 entries
Previous1Next
Data Current through: Sunday, Nov 5, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

GEODIS
We logistic your growth

GEODIS LOGISTICS LLC
[redacted] Executive Center Drive, Suite [redacted]
Brentwood, TN 37027
([redacted]
Organized in Tennessee on 02/08/1996

Sole Member and 100% Owner is Ozburn-Hessey Holding Company, LLC

Officers:

Mike Honious, President and CEO
[redacted] Executive Center Drive, Suite [redacted]
Brentwood, TN 37027

Jeremy Wright - EVP & Chief Financial Officer
[redacted]Executive Center Drive, Suite [redacted]
Brentwood, TN 37027

Mark Vane, Chief Legal Officer and Secretary
[redacted]Executive Center Drive, Suite [redacted]
Brentwood, TN 37027

Agent:
Corporation Service Company
[redacted]North Curry Street
Carson City, NV 89703

Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

GINA RUDOLPH
[redacted] EXECUTIVE CENTER DRIVE
BRENTWOOD, TN 37027

August 8, 2023

Request Type: Certificate of Existence/Authorization
Request #: 0541696

Issuance Date: 08/08/2023
Copies Requested: 1

Document Receipt

Receipt # : 008294027 — Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC #: 3856074759 — $20.00

Regarding: **Geodis Logistics LLC**
Filing Type: Limited Liability Company - Domestic
Formation/Qualification Date: 02/08/1996
Status: Active
Duration Term: Perpetual
Business County: WILLIAMSON COUNTY

Control # : [redacted]
Date Formed: 02/08/1996
Formation Locale: TENNESSEE
Inactive Date:

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

Geodis Logistics LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 062155215

STATE OF GEORGIA
Georgia Board of Pharmacy
Third Party Distributor
LICENSE NO. PHTPL000032 Status: Active

Geodis Logistics LLC
[redacted] Executive Center Dr
Suite [redacted]
Brentwood TN 37027

Expires: 06/30/2025
Issued: 09/20/2021

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Third Party Distributor** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Third Party Distributor
LICENSE NO. PHTPL000032 Status: Active
Geodis Logistics LLC
1004 Trade Center Pkwy
Suite100
Rincon GA 31326

Expires: 06/30/2025
Issued: 09/20/2021
Real-time license verification is available at gadch.mylicense.com/verification

Licensee Information

Name: Geodis Logistics LLC

Owner:

DBA:

Address: [redacted] Executive Center Dr
Suite [redacted]
Brentwood TN 37027

Primary Source License Information

Profession:	Pharmacy	**License No:**	[redacted]	**License Status:**	Active
License Type:	Third Party Distributor	**Obtained By Method:**	Application	**License Subtype:**	
Issue Date:	9/20/2021	**Expiration Date:**	6/30/2025	**Last Renewal Date:**	8/18/2023

Discipline Information

- Public Board Orders -

If a public board order exists, it may be listed below.
Public Board Order means that there is a public document concerning the licensee.
The existence of a public Board order does not necessarily mean the licensee is currently under any type of disciplinary action.

Please understand that the absence of a scanned order linked to this record does not necessarily mean that no public actions exist.

No scanned public board order documents exist.

Associated Licenses

No data available

You may close this window to return to your search results

Data current as of: November 6, 2023 14:3:18
This website is to be used as a primary source verification for licenses issued by the Boards of Dentistry and Pharmacy. Paper verifications are available for a fee. Please contact the Boards of Dentistry and Pharmacy at [redacted]

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
01/08/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Willis Towers Watson Southeast, Inc
Five Concourse Corporate Center, 18th Floor
Atlanta, GA 30328

CONTACT NAME: Willis Towers Watson Certificate Center
PHONE (A/C, No, Ext): [redacted] FAX (A/C, No): 1-888-467-2378
E-MAIL ADDRESS: [redacted]

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Old Republic Insurance Company	24147
INSURER B:	ACE Property & Casualty Insurance Company	20699
INSURER C:	Indemnity Insurance Company of North Ameri	43575
INSURER D:	ACE American Insurance Company	22667
INSURER E:		
INSURER F:		

INSURED
Orkin, LLC
Orkin Services of California, Inc.
Orkin Pest Control / Orkin Commercial Services
2170 Piedmont Road
Atlanta, GA 30324

COVERAGES **CERTIFICATE NUMBER:** W27860779 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR X Pesticide/Herbicide Coverage X Pest Control Professional GEN'L AGGREGATE LIMIT APPLIES PER: POLICY X PRO-JECT X LOC OTHER:			MWZY 312034-23	01/01/2023	01/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 3,000,000 $ 3,000,000 $ 0 $ 3,000,000 $ 3,000,000 $ 3,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			MWTB 312033-23	01/01/2023	01/01/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 3,000,000 $ $ $
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 50,000			XEU G27927683 008	01/01/2023	01/01/2024	EACH OCCURRENCE AGGREGATE	$ 5,000,000 $ 5,000,000
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: No If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		WLR C50678544	01/01/2023	01/01/2024	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 2,000,000 $ 2,000,000 $ 2,000,000
D	Excess Workers Comp			WCU C50678325	01/01/2023	01/01/2024	E.L. Each Accident E.L. Disease-EA Emp E.L. Disease- Pol Lim	$2,000,000 $2,000,000 $2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Br 254
Br Name Savannah
Br Address 23 Bryce Industrial Drive Garden City GA 31405

CERTIFICATE HOLDER

Sunland Logistics Solutions
1004 Trade Center Pkwy
Rincon, GA 31326

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Jessica Graham

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SR ID: 23585453 BATCH: 2799488

Rollins, Inc. et al.
Policy Term: 1/1/2023 to 1/1/2024
Workers' Compensation and Employers Liability Policy Addendum

Coverage	Policy Number	Carrier	WC Coverage	EL Limits
Work Comp/EL	[redacted]	Indemnity Insurance Company of North America: covers states of AL,AR,CO,CT,DC,DE,HI,IA,ID,IL, IN,KS,KY,LA,MD,ME,MI,MN,MO,MS,MT NC,NE,NH,NJ,NM,NV,NY,OK,PA, RI, SC,SD, TN,TX,UT,VA,VT,WV - This policy also provides Stop Gap coverage for ND, OH WA, WY	Statutory	$2,000,000 Bodily Injury by Accident - Each Accident/$2,000,000 Each Employee Bodily Injury by Disease/$2,000,000 Policy Limit Bodily Injury by Disease
Work Comp/EL	[redacted]	ACE American Insurance Company: covers state of AZ, CA, MA & OR	Statutory	$2,000,000 Bodily Injury by Accident - Each Accident/$2,000,000 Each Employee Bodily Injury by Disease/$2,000,000 Policy Limit Bodily Injury by Disease
Work Comp/EL	[redacted]	ACE Fire Underwriters Insurance Company, covers state of WI	Statutory	$2,000,000 Bodily Injury by Accident - Each Accident/$2,000,000 Each Employee Bodily Injury by Disease/$2,000,000 Policy Limit Bodily Injury by Disease
Excess Work Comp/EL	[redacted]	ACE American Insurance Company coverage applies to the qualified self insured states of FL, GA & OH	Statutory	$2,000,000 Bodily Injury by Accident - Each Accident/$2,000,000 Each Employee Bodily Injury by Disease/$2,000,000 Policy Limit Bodily Injury by Disease

The Cincinnati Insurance Companies
CHANGE RIDER

To be attached to and form a part of Bond No. [redacted]

Executed by Geodis Logistics, LLC

as Principal and by The Cincinnati Insurance Company as Surety,

in favor of Nevada : State Board of Pharmacy

as Obligee for the term beginning 11/21/2023 .

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to revise the information contained in the original bond as follows:

Adding additional locations and increasing bond to $400,000 from $300,000 (see attached schedule of locations)

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated. This rider is effective on the 21st day of November, 2023.

Geodis Logistics, LLC
Principal

Executed by:

By The Cincinnati Insurance Company
Surety

CINCINNATI OHIO

Andrea Leach
Andrea Leach Attorney-in-fact

F-650 (7/18)

THE CINCINNATI INSURANCE COMPANY
THE CINCINNATI CASUALTY COMPANY

Fairfield, Ohio [redacted]

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That THE CINCINNATI INSURANCE COMPANY and THE CINCINNATI CASUALTY COMPANY, corporations organized under the laws of the State of Ohio, and having their principal offices in the City of Fairfield, Ohio (herein collectively called the "Companies"), do hereby constitute and appoint

Andrea Leach

of NASHVILLE TN
their true and legal Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign, execute, seal and deliver on behalf of the Companies as Surety, any and all bonds, policies, undertakings or other like instruments, as follows:

Four Hundred Thousand Dollars $ 400,000.00

This appointment is made under and by authority of the following resolutions adopted by the Boards of Directors of The Cincinnati Insurance Company and The Cincinnati Casualty Company, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the President or any Senior Vice President be hereby authorized, and empowered to appoint Attorneys-in-Fact of the Company to execute any and all bonds, policies, undertakings, or other like instruments on behalf of the Corporation, and may authorize any officer or any such Attorney-in-Fact to affix the corporate seal; and may with or without cause modify or revoke any such appointment or authority. Any such writings so executed by such Attorneys-in-Fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company.

RESOLVED, that the signature of the President or any Senior Vice President and the seal of the Company may be affixed by facsimile on any power of attorney granted, and the signature of the Secretary or Assistant Vice-President and the Seal of the Company may be affixed by facsimile to any certificate of any such power and any such power of certificate bearing such facsimile signature and seal shall be valid and binding on the Company. Any such power so executed and sealed and certified by certificate so executed and sealed shall, with respect to any bond or undertaking to which it is attached, continue to be valid and binding on the Company.

IN WITNESS WHEREOF, the Companies have caused these presents to be sealed with their corporate seals, duly attested by their President or any Senior Vice President this 16th day of March, 2021.

THE CINCINNATI INSURANCE COMPANY
THE CINCINNATI CASUALTY COMPANY

Stephen A. Ventre

STATE OF OHIO)SS
COUNTY OF BUTLER)

On this 16th day of March, 2021 before me came the above-named President or Senior Vice President of The Cincinnati Insurance Company and The Cincinnati Casualty Company, to me personally known to be the officer described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of said Companies and the corporate seals and the signature of the officer were duly affixed and subscribed to said instrument by the authority and direction of said corporations.

Keith Collett, Attorney at Law
Notary Public – State of Ohio
My commission has no expiration date.
Section 147.03 O.R.C.

I, the undersigned Secretary or Assistant Vice-President of The Cincinnati Insurance Company and The Cincinnati Casualty Company, hereby certify that the above is the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Power of Attorney is still in full force and effect.

Given under my hand and seal of said Companies at Fairfield, Ohio, this 5th day of October, 2023

BN-1457 (3/21)

B-6749120

MULTI LOCATION SCHEDULE

Current Schedule as of 11/21/2023

LOCATION	ACCOUNT NAME & ADDRESS	BOND AMOUNT
1.	[redacted] Gateway Commerce Center Dr. East Edwardsville, IL 62025	$100,000.00
2.	1004 Trade Center Pkwy, Suite 100 Rincon, GA 31326	$100,000.00
3.	[redacted] Executive Center Dr Brentwood, TN 37027	$100,000.00
4.	[redacted] State Route 42 [redacted] McDonough, GA 30252	$100,000.00

McGriff

Remit to:
P.O. Box 890635
Charlotte, NC 28289-0635

00000512923100000-22GE0DIL0G6022000007007632000008000008

---------- INVOICE ----------

Geodis Logistics LLC
7101 Executive Center Drive
Brentwood, TN 37027

Invoice Date 10/09/23
Invoice No. 5129231
Bill-To Code [redacted]
Client Code
Inv Order No. 22*7007632

Named Insured: Geodis Logistics LLC

Amount Remitted: $

Please return this portion with your payment.

Make checks payable to: McGriff Insurance Services LLC

Effective Date	Policy Period	Coverage Description	Transaction Amount
11/21/23	11/21/23 to 11/21/24	The Cincinnati Insurance Company Policy No. [redacted] Renewal - Surety Bonds	8,000.00
		NV Wholesaler bond increased to $400,000 additional locations	
		Invoice Number: 5129231 Amount Due:	8,000.00

Due upon Receipt or Effective Date, whichever is later | *NEW* Pay with Credit Card/ACH: https://mcgriff.epaypolicy.com

ORIGINAL INVOICE

Christopher Mitchell

[redacted] Drake Drive
Richmond Hill, GA 31324
[redacted]

OBJECTIVE

To obtain a leadership position where I can maximize my multilayer leadership skills, project management, coaching, and successful track record in the supply chain management environment

PROFESSIONAL EXPERIENCE

GEODIS, *Rincon, GA*
Operations Director, September 2017-Current

- Directly responsible for all financial results, performance metrics, staffing needs, and building maintenance as a 3PL warehouse manager for a medical manufacturer and supplier
- Leverage safety solutions team to surpass 5 years without a recordable injury
- Lead 3 direct reports at multiple customer accounts that generate over 2.4M in annual revenue
- Trained 26 salaried leaders in the new GEODIS inventory control/DPPM (defective parts per million) program as Statesville campus trainer
- Created engagement program that helped reduce the GEODIS Savannah attrition rate from 70% to 30% year over year
- Reduced customer cost per unit by $0.08 from developing an alternative 4-day workweek schedule

Pier 1 Imports, *Pooler, GA*
DC Supervisor, January 2017-September 2017

- Achieved a 1.8 injury rate on a goal of 6.0 as building safety manager
- Established 'Blue Card Program' to help associates identify and correct unsafe situations
- Increased number of pickers at or above 100% productivity from 35% of the team to 83% of the team
- Developed "Conveyor Team Playbook" in receiving, increasing receiving production rates by 18%
- Led a Kaizen event that yielded a 13% reduction in labor in our transfer area

Target Corporation, *Midway, GA*
Operations Manager, June 2012-December 2016

- Responsible for the results of 40-60 team members daily
- Led night shift team to meet Level of Service (LOS) goals as Production Controller; in 2016 ranked 1st in pyramid in total building LOS
- As a Certified Executive Trainer, successfully on boarded 3 new Operations Managers in breakpack department
- Created inbound WIPs research routine reducing our defects by 21%, saving an average of $15,000 weekly, and moving from 21st to 8th in the Target DC pyramid in quality
- Coordinated a capacity re-racking plan that yielded a 6% increase in building capacity
- Reduced Inbound department injury rate from 16.7 to 6.2, driven by Safety Huddle processes
- Increased MBP LOS from 94% to 97% by creating new breakpack pick sequence

EDUCATION

Georgia Southern University
BBA in Logistics/Intermodal Transportation, Marketing

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Geodis Logistics LLC — MDEG License # (if applicable): n/a

Physical Address: 1004 Trade Center Pkwy, Suite 100

City: Rincon — State: GA — Zip: 31326

Mailing Address (if different from physical address): 7101 Executive Center Dr, Suite 333

City: Brentwood — State: TN — Zip: 37027

Telephone: 912-346-7501 — Website: www.geodis.com

Licensing Company Email: licensing.cl.us@geodis.com

Section 2: Personal Information

First: Christopher — Middle: Ryan — Last: Mitchell

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Drake Drive, Richmond Hill, [redacted]

City: Richmond Hill — State: GA — Zip: 31324

Telephone: [redacted] — Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Georgia Southern University		08/06 - 05/12	
Address	**City**	**State**	**Zip**
1332 Southern Dr	Statesboro	GA	30458
Diploma/Degree obtained, if any			
Bachelors in Logistics and Intermodal Transportation			

School Name		From - To (MM/YY – MM/YY)	
Houston County High School		08/02 - 05/06	
Address	**City**	**State**	**Zip**
920 SR 96	Warner Robins	GA	31088
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/19 - Present	[redacted]Dove Drake Drive	Richmond Hill	GA	31324
03/17 - 06/19	[redacted]Twelve Oaks Road	Port Wentworth	GA	31407
03/15 - 03/17	[redacted]Timberland Gap	Pooler	GA	31322

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Geodis Logistics LLC			09/17 - Present	
Business Address		**City**	**State**	**Zip**
1004 Trade Center Pkwy, Suite 100		Rincon	GA	31326
Phone	**Title**		**Number of Employed Hours**	
912-346-7501	Director of Operations		11,040	
Description of Duties				
Overall duty of managing, directing, compliance, financial performance, warehouse operations, staffing, and productivity.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/25/2006	1/22/2007	GA	Byron	Peach

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
[redacted]	Byron Police Department/Byron Municipal Court

Reason/Charge
DUI - DRIVING UNDER THE INFLUENCE OF ALCOHOL

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
n/a	n/a

Name of Business/Industry/Entity
n/a

Provide explanation below:

On 11/25/2006, Chris Mitchell was pulled over for Driving Under the influence of alcohol. On 1/22/2007 Byron Municipal Court dismissed the case.

Original Signature (electronic, copies or stamps not accepted)

11/17/2023
Date

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/05/2007	06/18/2007	GA	Statesboro	Bulloch
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		GEORGIA SOUTHERN UNIVERSITY DPS/BULLOCH COUNTY STATE COURT		
Reason/Charge				
WILLFUL OBSTRUCTION OF LAW ENFORCEMENT OFFICERS; FURNISHING TO, PURCHASE OF, OR POSSESSION BY PERSONS BELOW LEGAL AGE OF ALCOHOLIC BEVERAGES.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
n/a		n/a		
Name of Business/Industry/Entity				
n/a				

Provide explanation below:

On 5/5/07, Chris Mitchell was at a college party and law enforcement arrived. Several individuals ran in the midst of Chris being apprehended. The encounter resulted in Chris being charged with WILLFUL OBSTRUCTION OF LAW ENFORCEMENT OFFICERS and FURNISHING TO, PURCHASE OF, OR POSSESSION BY PERSONS BELOW LEGAL AGE OF ALCOHOLIC BEVERAGES.

Original Signature (electronic, copies or stamps not accepted)

11/17/2023
Date

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
09/27/2008		GA	Statesboro	Bulloch
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		GEORGIA SOUTHERN UNIVERSITY DPS		
Reason/Charge				
Theft By Taking				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
n/a		n/a		
Name of Business/Industry/Entity				
n/a				

Provide explanation below:

On 9/27/08. Chris Mitchell was and a group of individuals were at a college tailgating party and were arrested for taking alcoholic beverages from a cooler that did not belong to them.

Original Signature (electronic, copies or stamps not accepted)

11/17/2023
Date

I, Christopher Mitchell, **certify that as the MDEG Administrator for**

Geodis Logistics LLC,

that I (initial that you have read and meet the following requirements):

1. CM Have a high school diploma or its equivalent;
2. CM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Mitchell
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/17/2023
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Y

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Geodis Logistics LLC

Pharmacy/Wholesaler License # (if applicable): n/a

Physical Address: 1004 Trade Center Pkwy, Suite 100

City: Rincon State: GA Zip: 31326

Mailing Address (if different from physical address): 7101 Executive Center Dr, Suite 333

City: Brentwood State: TN Zip: 37027

Telephone: 912-346-7501 Website: www.geodis.com

Licensing Company Email: licensing.cl.us@geodis.com

Section 2: Personal Information

First: Christopher Middle: Ryan Last: Mitchell

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Drake Drive

City: Richmond Hill State: GA Zip: 31324

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Georgia Southern University		08/06 - 05/12	
Address	**City**	**State**	**Zip**
1332 Southern Dr	Statesboro	GA	30458
Diploma/Degree obtained, if any			
Bachelors in Logistics and Intermodal Transportation			

School Name		From - To (MM/YY – MM/YY)	
Houston County High School		08/02 - 05/06	
Address	**City**	**State**	**Zip**
920 SR 96	Warner Robins	GA	31088
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/19 - Present	[redacted]Dove Drake Drive	Richmond Hill	GA	31324
03/17 - 06/19	[redacted]Twelve Oaks Road	Port Wentworth	GA	31407
03/15 - 03/17	[redacted]Timberland Gap	Pooler	GA	31322
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Geodis Logistics LLC			09/17 - Present	
Business Address		**City**	**State**	**Zip**
1004 Trade Center Pkwy		Rincon	GA	31326
Phone	**Title**		**Number of Employed Hours**	
912-346-7501	Director of Operations		11,040	
Description of Duties				
Overall duty of managing, directing, compliance, financial performance, warehouse operations, staffing, and productivity.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/25/2006	01/22/2007	GA	Byron	Peach
Case # [redacted]		**Governing, licensing, Arresting Presiding Body/Agency/Court** Byron Police Department/Byron Municipal Court		
Reason/Charge DUI - DRIVING UNDER THE INFLUENCE OF ALCOHOL				
Plaintiff/Defendant/Claimant/Respondent n/a			**Lawsuit/Arbitration/Bankruptcy** n/a	
Name of Business/Industry/Entity n/a				

Provide explanation below:

On 11/25/2006, Chris Mitchell was pulled over for Driving Under the influence of alcohol. On 1/22/2007 Byron Municipal Court dismissed the case.

Original Signature (electronic, copies or stamps not accepted)

11/17/2023
Date

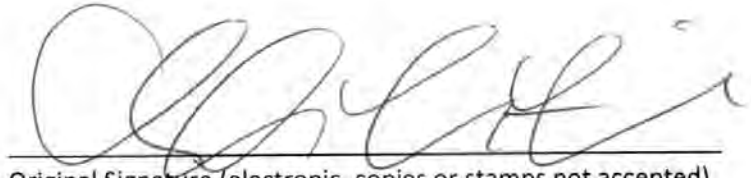
Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/05/2007	06/18/2007	GA	Statesboro	Bulloch
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		GEORGIA SOUTHERN UNIVERSITY DPS/BULLOCH COUNTY STATE COURT		
Reason/Charge				
WILLFUL OBSTRUCTION OF LAW ENFORCEMENT OFFICERS; FURNISHING TO, PURCHASE OF, OR POSSESSION BY PERSONS BELOW LEGAL AGE OF ALCOHOLIC BEVERAGES.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
n/a		n/a		
Name of Business/Industry/Entity				
n/a				

Provide explanation below:

On 5/5/07, Chris Mitchell was at a college party and law enforcement arrived. Several individuals ran in the midst of Chris being apprehended. The encounter resulted in Chris being charged with WILLFUL OBSTRUCTION OF LAW ENFORCEMENT OFFICERS and FURNISHING TO, PURCHASE OF, OR POSSESSION BY PERSONS BELOW LEGAL AGE OF ALCOHOLIC BEVERAGES.



Original Signature (electronic, copies or stamps not accepted)

10/17/2023

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
09/27/2008		GA	Statesboro	BULLOCH
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		GEORGIA SOUTHERN UNIVERSITY DPS		
Reason/Charge				
Theft By Taking				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
n/a		n/a		
Name of Business/Industry/Entity				
n/a				

Provide explanation below:

On 9/27/08. Chris Mitchell was and a group of individuals were at a college tailgating party and were arrested for taking alcoholic beverages from a cooler that did not belong to them.

Original Signature (electronic, copies or stamps not accepted)

11/17/2023
Date

I, Christopher Mitchell, **certify that as the designated representative for**

Geodis Logistics LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CM I am at least 21 years of age;
3. CM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Mitchell
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/17/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Mitchell

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/5/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Georgia, ss. County of Effingham

I, Christopher Ryan Mitchell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-5-23

Date

Subscribed and Sworn to before me this 5 day of July 2023

Notary Public Signature

EMILY MILLER
NOTARY PUBLIC
My Commission Expires
07-05-2026
EFFINGHAM COUNTY, GEORGIA
(Seal)

List of Employees

EMPLOYEE ROSTER	STATUS	POSITION
Ash, Keaunna	ACTIVE	OP1
Beckett, Michael A	ACTIVE	IC
Blige, Tyrone	ACTIVE	OP1
Bobian, Chantel	ACTIVE	OP2
Bowman, Sharon	ACTIVE	CSR
Caudill, Pam	ACTIVE	LEAD
Clark, Chris	ACTIVE	SANI
Crowe, Tim	ACTIVE	LEAD
Dillard, Maurice L	SALARY	SUP
Exley, Yaires	ACTIVE	OP2
Gilliam, Taj	ACTIVE	IC
Grimes, Jaquan	ACTIVE	OP2
Harris, Devaughn	ACTIVE	OP1
Hill, Seven	ACTIVE	LEAD
Inabinett, Delric D	ACTIVE	LEAD
Jackson, Cherlene	ACTIVE	OP1
Martin, Mylania	ACTIVE	CSR
Mayers, Jessica	ACTIVE	AUDITOR
McChargue, Dave	ACTIVE	OP2
McIntyre, Stefon	ACTIVE	OP1
Mikell, Greg	ACTIVE	OP2
Mills, Shannon	SALARY	OM
Mitchell, Chris	SALARY	DIRECTOR
Perry, Antrenita *Faye*	SALARY	SUP
Rhynes, Kureem	ACTIVE	OP1
Smith, Pantez	ACTIVE	OP1
Smith, Reginald	ACTIVE	OP1
Spann, Adrian	ACTIVE	OP1
Thomas, Dorothea	SALARY	SUP
Wevers, Cara	SALARY	AOM

12C

13

13A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ■ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02088	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Alcami Carolinas Corporation (formerly Pacific Pharmaceutical Services)

Physical Address: 4850 JOULE ST #A-8

City: Reno State: NV Zip: 89502

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (775) 240-1607 Website: www.alcaminow.com

Name of Designated Representative (DR): Jeffrey Michael Evans

Licensing Company Email: regulatory.submissions@alcami DR Email: jeff.evans@alcaminow.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Pharma products	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Pharma industry		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): _____

Corporation/Organization Name: Alcami Corporation

Mailing Address: 4620 Creekstone Drive

City: Durham State: NC Zip: 27703

Telephone: 1 910-254-7000 Email: kenneth.morgan@alcaminow.com

Contact Person Name: Kenneth Morgan

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Alcami Carolinas Corporation

Facility Name

Sonia Smith

Print Name of Authorized Person Submitting Application

Sonia Smith

Original signature of Authorized Person (copies or stamps not accepted)

May 28, 2024

Date

Board Use Only	Date Received: _____	Amount: _____

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New Search

Search Results for *Alcami*

Showing 1 to 1 of 1 entries (filtered from 16 total entries)

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Alcami Carolinas Corporation	3010163990	119255340	MANUFACTURE	4850 Joule St Ste A-8, Reno, Nevada (NV) 89502-4150, United States (USA)	12/31/2024

Previous 1 Next

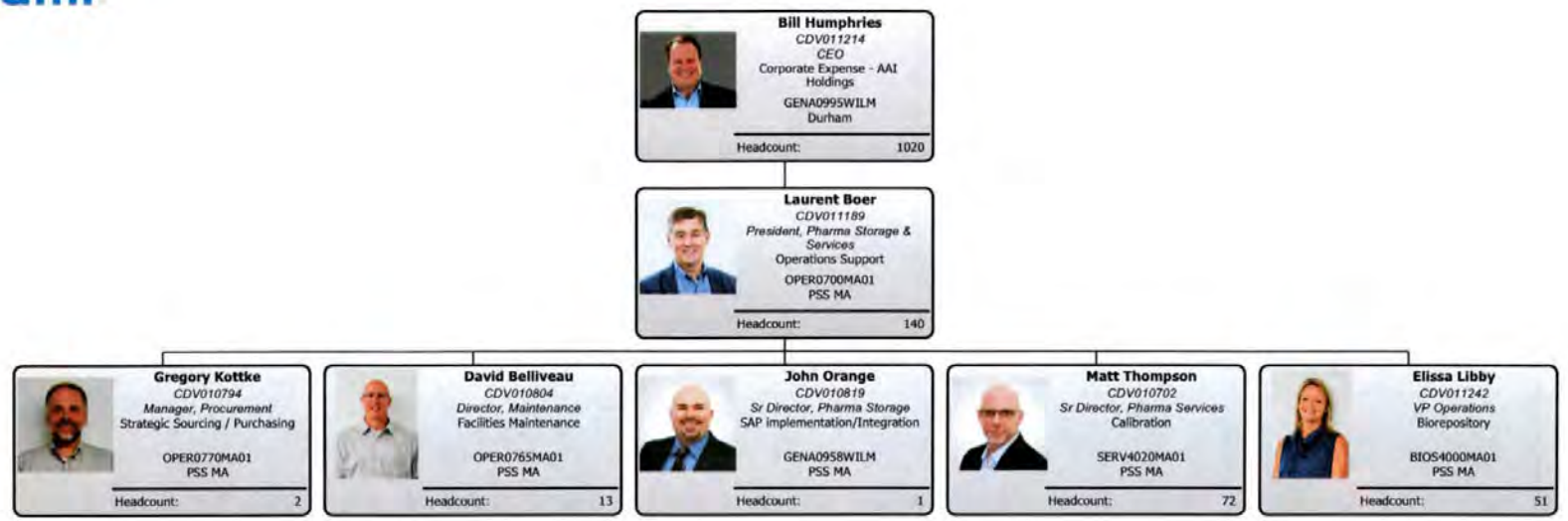
Data Current Through: Friday, Jun 07, 2024

New Search

alcami

Operations Support

Intern
Temp/Contractor
Management Rep

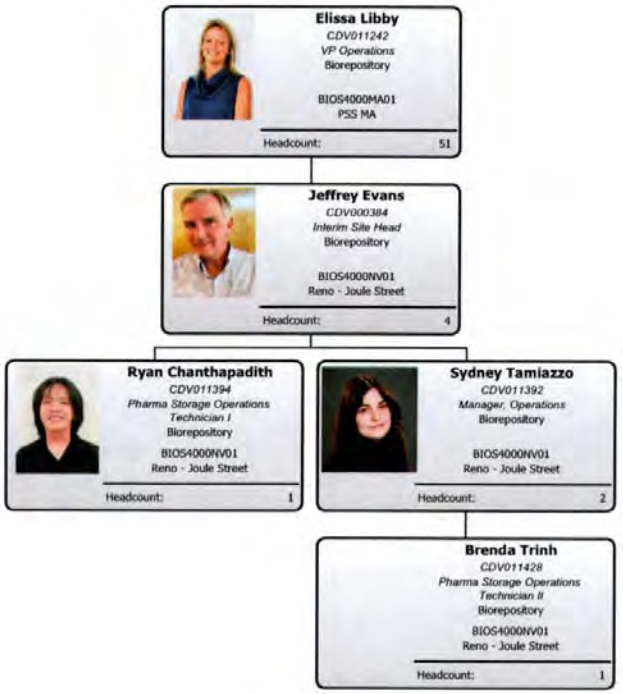


Last Refreshed: May 27, 2024

alcami

Biorepository

Intern
Temp/Contractor
Management Rep

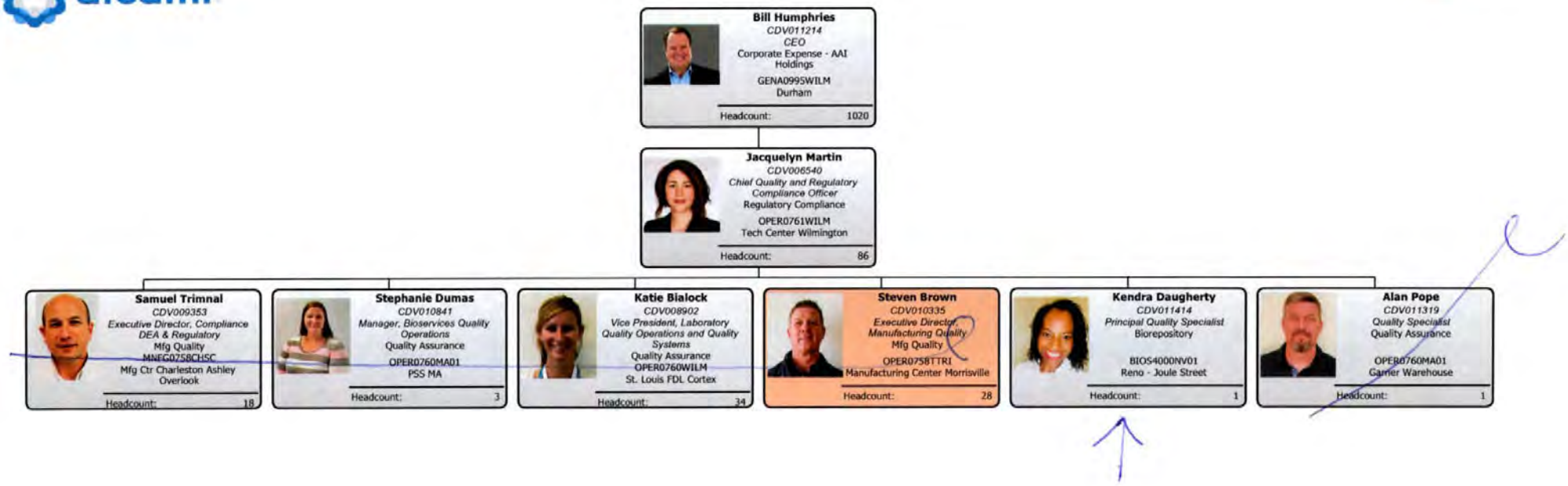


Last Refreshed: May 27, 2024

alcami

Regulatory Compliance

Intern
Temp/Contractor
Management Rep



Last Refreshed: May 27, 2024

Number
-2-

Shares
- 1,000 -

PACIFIC PHARMACEUTICAL SERVICES, INC.

SEE REVERSE SIDE FOR RESTRICTIONS ON TRANSFER

This certifies that **ALCAMI CORPORATION** is the owner of **One Thousand and 00/100 (1,000)** shares, fully paid and nonassessable, of the Common Stock of **PACIFIC PHARMACEUTICAL SERVICES, INC.**, a Nevada corporation, transferable only on the books of the corporation by the holder hereof in person or by attorney upon surrender of this certificate properly endorsed.

This certificate and the shares represented hereby are subject to the laws of the State of Nevada and to the Certificate of Incorporation and the Bylaws of the corporation, in each case as from time to time amended.

IN WITNESS WHEREOF, **PACIFIC PHARMACEUTICAL SERVICES, INC.** has caused this certificate to be signed by its duly authorized officers this ____ day of _____, 2024.

William Humphries, Chief Executive Officer

Kenneth Morgan

Kenneth Morgan, Chief Financial Officer

Attachment 1

Attachment 3

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALCAMI CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTH DAY OF FEBRUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ALCAMI CORPORATION" WAS INCORPORATED ON THE TWENTY-THIRD DAY OF JUNE, A.D. 2009.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4701035 8300

SR# 20240407421

Authentication: 202763979

Date: 02-07-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

2024

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
1368

LICENSE/CERTIFICATE: Manufacturer
TYPE PRESCRIPTION DRUG LICENSE
Expiration Date 12/31/2024

ENSEE Alcami Carolinas Corporation dba Alcami Corporation
or Alcami
RTIFICATOR 627 Davis Drive, Suite 100
Morrisville NC 27560

LICENSED
2024
NORTH CAROLINA

IIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

Steven W. Troxler
STEVE TROXLER, COMMISSIONER

Attachment 5
182

2024

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
424

NOT TRANSFERABLE
STATUTE GS 81.106.119

LICENSE/CERTIFICATE: Manufacturer
TYPE PRESCRIPTION DRUG LICENSE
Expiration Date 12/31/2024

ENSEE Alcami Corporation
2320 Scientific Park Drive
RTIFICATOR Wilmington NC 28405

LICENSED
2024
NORTH CAROLINA

IIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

Steve W. Troxler
STEVE TROXLER, COMMISSIONER

Attachment 5
Pg 2

1 of 1

Attachment 6

60
ALCAMI CAROLINAS CORPORATION
4221 FABER PLACE DRIVE
CHARLESTON SC 29405

PERMIT NO. 16896
DATE ISSUED: 06/06/2023

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

Manufacturer/Repackager

2023-2024

Expires 06/30/2024

ALCAMI CAROLINAS CORPORATION

Permit Holder: SONIA SMITH
4221 FABER PLACE DRIVE
CHARLESTON SC 29405

Traci Collier
Traci Collier, Administrator

Heather C. Harris
Heather C. Harris, Board Chair

Archie "Artie" McKnight, Vice Chair

17 of 17

Attachment 2

SureTec Insurance Company
2103 City West Boulevard, Suite 1300, Houston, TX 77042

CONTINUATION CERTIFICATE

Friday, November 24, 2023

BOND NUMBER	BOND DESCRIPTION	BOND AMOUNT	EFFECTIVE DATE	EXPIRATION DATE
5296180	NV / Pharmaceutical Wholesaler Bond	$25,000.00	2/12/2024	2/11/2025

Principal:

PACIFIC PHARMACEUTICAL SERVICES LLC

Obligee:

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Ste 206
Reno, NV 89521

THIS BOND CONTINUES IN FORCE TO THE ABOVE EXPIRATION DATE CONDITIONED AND PROVIDED THAT THE LOSSES OR RECOVERIES IN IT AND ALL ENDORSEMENTS SHALL NEVER EXCEED THE PENALTY SET FORTH IN THE BOND AND WHETHER THE LOSSES OR RECOVERIES ARE WITHIN THE FIRST AND/OR SUBSEQUENT OR WITHIN ANY EXTENSION OR RENEWAL PERIOD, PRESENT, PAST OR FUTURE. ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.

Signed and dated this 24 day of November, 2023.

SURETEC INSURANCE COMPANY TEXAS

SureTec Insurance Company

Joshua Kayser , Attorney in Fact

Agent:

BROOKLYN VENTURES, LLC
803 E. WALNUT STREET., 5TH FLOOR
COLUMBIA, MO 65201

12 of 17

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 108041029

Application/License No. WHO 2088

Alcami Carolinas Corporation dba Alcami Corporation (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4850 Joule Street, Reno, NV 89502 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square , Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 17, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 17th day of May, 2024.

APPLICANT/PRINCIPAL

Alcami Carolinas Corporation dba Alcami Corporation

By: _____
Authorized Representative

SURETY COMPANY

Travelers Casualty and Surety Company of Ameri

By: _____
Surety Company's Representative

Hillary D. Shepard, Attorney-in-fact
print name
Nevada License #3436995

Surety Phone No. 860-277-0111

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Rosanna Dabler

N/A
Witness

Countersigned by:

_____
Nevada Resident Agent N/A

Posted February 20, 2020

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company
Farmington Casualty Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint Hillary D. Shepard of Kansas City , MO , their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge the following bond:

Surety Bond No.: 108041029
OR
Project Description: NV Pharmaceutical Wholesaler Bond

Principal: Alcami Carolinas Corporation dba Alcami Corporation
Obligee: Nevada State Board of Pharmacy

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021.**

State of Connecticut

By: _____
Robert L. Raney, Senior Vice President

City of Hartford ss.

On this the **21st** day of **April, 2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 17th day of May , 2024 .

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Pacific Pharmaceutical Services dba Alcami Carolinas Corporation

Pharmacy/Wholesaler License # (if applicable): WH02088

Physical Address: 4850 Joule St #A-B

City: Reno State: NV Zip: 89502

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website: www.alcaminow.com

Licensing Company Email: regulatory.submissions@alcaminow.com

Section 2: Personal Information

First: Jeffrey Middle: Michael Last: Evans

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Reno State: NV Zip: 89523

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Syracuse University		09/87-12/92	
Address	City	State	Zip
	Syracuse	NY	
Diploma/Degree obtained, if any			
PhD Organic Chemistry, M Phil Chemistry			

School Name		From - To (MM/YY – MM/YY)	
State University of New York at Oswego		09/81-09/87	
Address	City	State	Zip
	Oswego	NY	
Diploma/Degree obtained, if any			
BSc Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Bishop Grimes High School			
Address	City	State	Zip
	East Syracuse	NY	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/21-present	[redacted]	Reno	NV	89523
12/18-12/21		Lake Placid	NY	12946
08/14-12/18		Bainbridge	NY	13733
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Pacific Pharmaceuticals			From - To (MM/YY – MM/YY): 11/21-present
Business Address: 4850 Joule St	City: Reno	State: NV	Zip: 89502
Phone: 775-240-1607	Title: VP Operations		Number of Employed Hours: 6,000
Description of Duties: Responsible for managing and executing operations of company including dispensing, and distribution.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

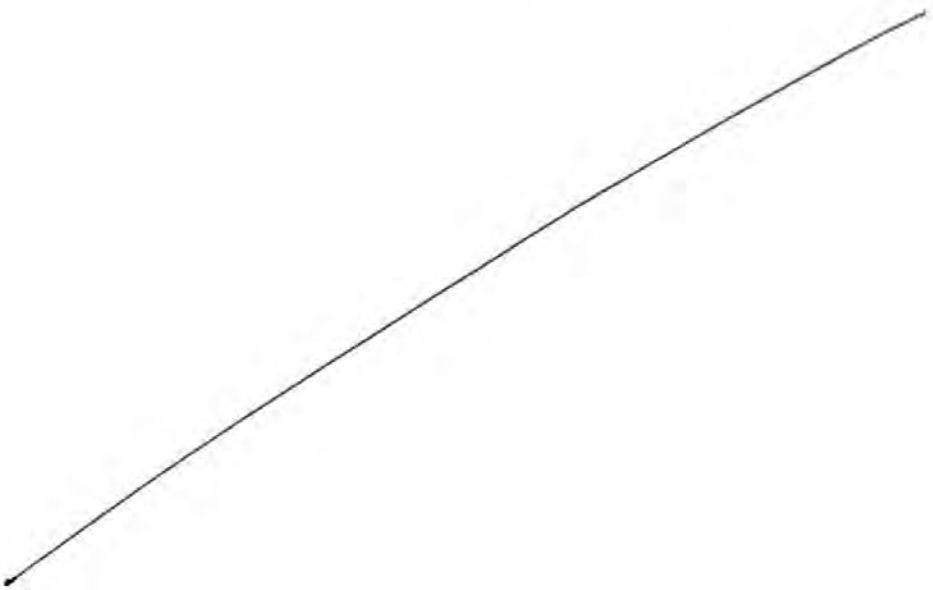
Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

Date

I, Jeffrey Evans **, certify that as the designated representative for**

Pacific Pharmaceutical Services dba Alcami Carolinas Corporation ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JME I am at least 21 years of age;
3. JME I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JME I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JME I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JME I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JME I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jeffrey Evans

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

14 February, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Evans

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

14 February 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Jeffrey Evans, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

14 FEB 2024

Date

Subscribed and Sworn to before me this 14 day of February.

Notary Public Signature

JOSE LUIS BOBADILLA
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 12-29-25
Certificate No: 21-5758-02

(Seal)

Date: May 28, 2024

To: Maria Herrera
State of Nevada Board of Pharmacy

From: Sonia Smith, Alcami Carolinas Corporation, Director Regulatory Affairs

Subject: Updated information to reflect name change to Alcami Carolinas Corporation from Pacific Pharmaceutical Services

Specific details:

Thank you for the information regarding the updated documents needed for the company name change from Pacific Pharmaceutical Services to Alcami Carolinas Corporation.

The following is provided per our discussion on April 30, 2024.

1. Updated Wholesaler Application with the Name Change box ticked, Facility Name stated as Alcami Carolinas Corporation in Section 1 and signature page.

2. Surety Bond issued in the name of Alcami Carolinas Corporation

3. Organizational Charts showing the reporting structure within the Alcami Carolinas Corporation (Quality and Operations).

The full list of Alcami Carolinas Corporation employees at located in Reno, Nevada:

1. Jeffrey Evans- Interim Site Head
2. Ryan Chanthapadith – Pharma Storage Operations Technician I
3. Sydney Tamlazzo – Manager, Operations
4. Brenda Trinh – Pharma Storage Operations Technician II
5. Kendra Daugherty – Principal Quality Specialist

Please do not hesitate to contact me if you have any questions about the content of the information provided. We will answer your questions expeditiously.

Sonia Smith
Director, Regulatory Affairs
Alcami Corporation
4620 Creekstone Drive, Suite 200, Durham, NC 27703
[redacted]
sonia.smith@alcaminow.com
www.alcaminow.com

Date: February 15, 2024

To: Nevada State Board of Pharmacy

From: Sonia Smith, Director Regulatory Affairs

Subject: Wholesaler Application for Pacific Pharmaceutical Services
WH02088 –Ownership Change

Specific details:
Alcami Corporation ("Alcami"), a leading contract development and manufacturing organization (CDMO), completed the acquisition of Pacific Pharmaceutical Services, Inc. ("PPS"), a preferred provider of cGMP pharma storage and services on January 17, 2024.

Alcami is a Contract Development and Manufacturing Organization (CDMO) specializing in all phases of pharmaceutical development – from critical pre-formulation studies to commercial manufacturing.

We wish to emphasize that PPS is a cGMP pharma storage provider, including cold storage. Additionally, PPS provides clinical labeling of investigational drug products and aliquoting of GMP materials under controlled conditions.

Accordingly, the updated Wholesaler Application indicating an Ownership Change is provided in this correspondence.

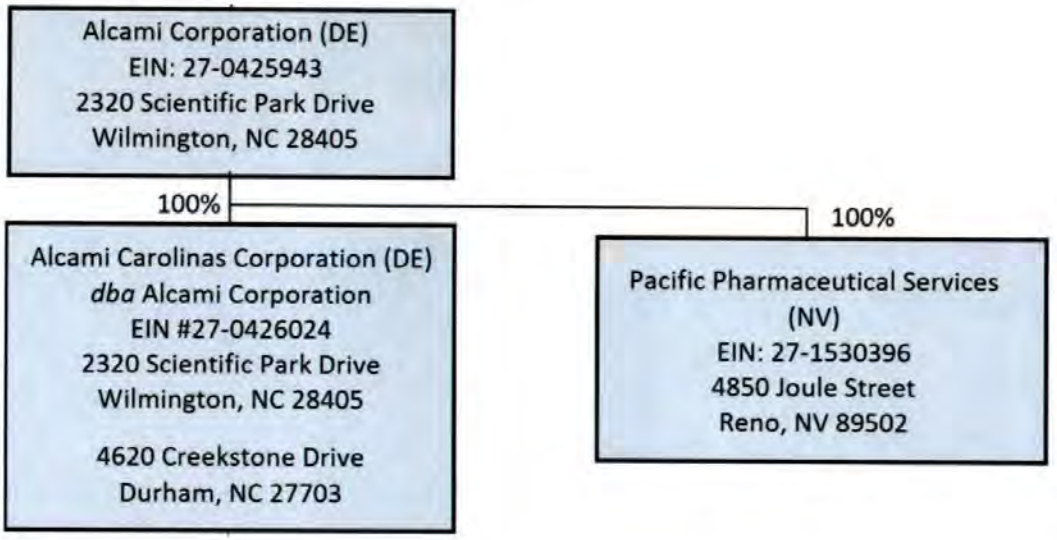
Scott Chadwick was the sole shareholder of Pacific Pharmaceutical Services ("PPS"), located in in Reno, Nevada

Alcami Corporation bought 100% of his shares. Please see the attached stock certificate certifying that Alcami Corporation is the owner of 1000 shares of the common stock of PPS (**Attachment 1**).

PPS is a corporation and a separate legal entity owned by Alcami Corporation. Furthermore, the officers of PPS did not change.

1717

ALCAMI CORPORATION 4620 Creekstone Drive Suite 200 Durham, NC 27703 +1 919.957.5500 www.alcaminow.com



Pursuant to the requirements defined in the Nevada State Board of Pharmacy Wholesaler Application, the following information is provided.

Section 1 General Information

PPS is a pharma storage and services business that serves biotech and pharma clients. The services include labeling and shipping of clinical drug product for clinical studies for pharma clients. Additionally, PPS provides aliquoting services of GMP and non-GMP material.

Accordingly, "Others" was checked for the "Entities the Wholesaler will Serve". Specifically, PPS will serve Pharma and Biotech companies by providing controlled storage, clinical labeling and shipping of investigational drug products, and aliquoting of materials.

With respect to "Products to be Handled or Wholesaled", we wish to emphasize that PPS handles GMP drug product and materials for Pharma and Biotech companies and does not wholesale drug products.

Section 2: History of Company

The information provided for this Section is specific to Alcami Corporation.

Section 8: NABP Accreditation/FDA Registration

2917

Personal History Record Application

Not required as no shareholder/stockholder/partner/owner owns more than 10% of the business stocks/shares.

Copy of DEA certificate if handling controlled substances

PPS does not handle controlled substances.

List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.

Not applicable as all employees of PPS moved to Alcami. Additionally, there is not a lender or holder of indebtedness of the applicant.

Copy of your license, certification, permit or registration issued to your wholesale business from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. (REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)

The current State of Nevada Wholesaler license for PPS is WH02088.

As detailed in this letter, Alcami is a Contract Drug Manufacturer Organization (CDMO). The licenses from North Carolina and South Carolina are provided in **Attachment 5** and **Attachment 6**, respectively.

Please do not hesitate to contact me if you have any questions about the Alcami Corporation manufacturing facilities with respect to this application.

Sonia Smith
Director, Regulatory Affairs
Alcami Corporation
4620 Creekstone Drive, Suite 200, Durham, NC 27703
[redacted]
sonia.smith@alcaminow.com
www.alcaminow.com

4 of 17

13B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Geryon Holdings, LLC D/B/A DESS-USA

Physical Address: 10765 Double R Blvd., Suite 200

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 855-337-7872 Website: www.dess-usa.com

Name of Designated Representative (DR): Curtis Darin Lockaby

Licensing Company Email: [redacted]@gmail.com DR Email: [redacted]@gmail.com darin.lockaby@dess-usa.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
6/5/2023	6/5/2023	NV	Reno	Washoe
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
23-153-N		Nevada Board of Pharmacy		
Reason/Charge				
Unlicensed furnishing of prescription medical devices				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
State of Nevada Board of Pharmacy		Cease and Desist Order and Fine		
Name of Business/Industry/Entity				
Geryon Holdings, LLC D/B/A DESS AND DESS USA				

Provide explanation below:

Company was ignorant of need to obtain Nevada Board of Pharmacy license for its wholesaler (distribution) activities. The Board issue a cease and desist and fine order on June 5, 2023. The company paid the fine, and is now submitting this application to come into compliance with state law.

Original Signature (electronic, copies or stamps not accepted)

4/24/24
Date

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Web Page: bop.nv.gov

June 5, 2023

Via Certified Mail and Email

DESS-USA
10765 Double R. Blvd., Suite 200
Reno, Nevada 89521

Attn: Jonas Grant, Esq.
jonas@jonasmgrant.com

CEASE-AND-DESIST and CITATION-AND-FINE ORDER: Case No. 23-153-N, Unlicensed Furnishing of Prescription Medical Devices

Dear Mr. Grant:

This letter responds to your letter dated June 1, 2023, in which you confirm that you represent Geryon Holdings, LLC, a Delaware limited-liability company doing business as DESS-USA (DESS). The Nevada State Board of Pharmacy (Board) has determined that DESS is engaged in the business of furnishing prescription medical devices in Nevada without having secured a license as required by Nevada Revised Statutes (NRS) 639.233. Pursuant to NRS 639.233, any manufacturer or seller of prescription medical devices must secure a Nevada license if it receives, stores, or ships such products within or into Nevada.

Under Nevada law, the term "drug" is defined to include "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans." *See* NRS 639.007. The terms "manufacturer" and "wholesaler" are defined at NRS 639.009 and NRS 639.016, respectively. The term "medical products provider" is defined at Nevada Administrative Code (NAC) 639.6936. Nevada licensure is required of any person, *including* a manufacturer, wholesaler, or medical products provider, who sells or ships drugs or medical devices "that are restricted by federal law to sale by or on the order of a physician to any person located within this State." *See* NRS 639.233(1) and (2); NAC 639.6942.

As suggested by your own letter, DESS is engaged in the business of selling "devices" as that term is defined at 21 U.S.C. § 321(h). To serve their intended purpose, these devices must be surgically implanted or affixed by a qualified medical practitioner such as a dentist or oral surgeon. Accordingly, the devices are "prescription devices" within the meaning of 21 CFR § 801.109. Federal regulations define these prescription devices more precisely as "endosseous dental implants," *see* 21 CFR § 872.3640, "endosseous dental implant accessories," *see* 21 CFR § 872.3980, and/or "endosseous dental implant abutments," *see* 21 CFR §§ 872.3630.

Because these devices are not safe to use for their intended purpose except under the supervision of a qualified medical practitioner, they must bear a label indicating that they are prescription-only devices. *See* 21 CFR § 109(b). Please consider the following:

- On or about April 27, 2023, Board Inspector Mui Lee visited the DESS facility, located at 10765 Double R. Blvd., Suite 200, in Reno, Nevada. There, she observed what appeared to be an inventory of endosseous dental components bearing "Rx only" labels.
- Employees Kim Ki and Joes Frey advised Ms. Lee that DESS sells such products from its location in Reno, Nevada.
- On or about May 15, 2023, during a conversation with Board Investigator Monica Segedy, Chief Executive Officer Robert Tobys confirmed the same.
- DESS maintains a website where it describes its devices as "FDA approved" dental "implant systems."

Given the above evidence, the Board rejects your contention that DESS devices are not restricted by federal law to sale by or on the order of a physician. The labeling on the devices directly rebuts this position. Even if DESS chooses to sell its devices directly to patients—as opposed to dentists and oral surgeons—it must secure a license pursuant to NRS 639.233. In short, it is immaterial whether DESS sells its devices at retail or at wholesale. Either way, DESS sells devices that are restricted by federal law to sale by or on the order of a physician.

Accordingly, the Board hereby orders DESS to immediately **CEASE and DESIST** furnishing to persons in Nevada any devices that are restricted by federal law to sale by or on the order of a physician. This includes, without limitation, all devices described in 21 CFR Part 872. Further, this notice shall serve as a **CITATION** pursuant to NRS 639.2895(2) for the unlicensed furnishing of medical devices to persons in Nevada. Pursuant to NRS 639.2895(3), the Board has assessed an **administrative fine** against DESS in the amount of **Five Thousand and 00/100 Dollars ($5,000.00).**

If your client does not intend to contest the above fine, please instruct your client to pay the fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check*, *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Your client may appeal this citation by submitting to the Board, at the Reno address listed above, a written request for a public hearing. You must submit any such request not later than 30 days after receipt of this notice. *See* NRS 639.2895(2). Additionally, please be aware that issuance of the foregoing letter does not preclude the filing of an administrative disciplinary complaint, a civil suit, or criminal charges, if deemed appropriate based upon evidence not currently available to the Board's investigative staff. If you have any questions, please do not

hesitate to contact me by telephone at 775-850-1440, ext. 124, or *via* email at zunino@pharmacy.nv.gov.

Sincerely,

/s/ Gregory L. Zunino
Gregory L. Zunino
Nevada State Board of Pharmacy
Senior General Counsel

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Sensis Invest, S.L., a Spanish sociedad limitada (limited liability company) (sole supplier)
Address: CL DE LA MOGODA 75-99 City: Barcelona State: Spain Zip: 08210

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada
Parent Company (if any): Sensis Invest USA, Inc., a Delaware corporation
Corporation/Organization Name: Geryon Holdings, LLC
Mailing Address: 10765 Double R Blvd., Suite 200
City: Reno State: NV Zip: 89521
Telephone: 855-337-7872 Email: [redacted]
Contact Person Name: Curtis Darin Lockaby

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Geryon Holdings, LLC D/B/A DESS-USA

Facility Name

Curtis Darin Lockaby

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4/24/24

Date

Board Use Only	Date Received: 4/25/24	Amount: $1000 check 1014

Geryon Holdings, LLC D/B/A DESS-USA

Attachment to Nevada State Board of Pharmacy Wholesaler Application

SECTION 9

List of all Directors and Officers

As a limited liability company, the company has no directors, but it has the following officers:

Darin Lockaby

Roger Terrats Bes

List of All Shareholders

Solely owned by Sensis Invest USA, Inc. a Delaware corporation

Sensis Invest USA, Inc. is in turn solely owned by Sensis Invest, S.L., a Spanish limited liability company

Sensis Invest, S.L.'s owners are as follows:

Miura Fund III F.C.R.	55.0207%	This is a fund which there isn't any owner with more than 10% shares
Taira Partners SCR, S.A.	11.1229%	This is a fund which there isn't any owner with more than 10% shares
Golden Leaf Investments, S.L.	14.4208%	Owned by Roger Terrats Bes
Monesmat, S.L	14.4208%	Owned by Ramon Terrats Bes
1418 Investments, S.L.	14.4208%	Owned by Jordi Terrats Bes
HEALTHCARE CONSULTANTS BERGLUND AB	0.5941%	

List of All Employees

Darin Lockaby – President

Carl DeCius – Controller

Ki Kim – Technical Support

Jenelle Eaton – Customer Service Manager

Joel Frey – Operations Manager

Alexis Clewett – Customer Service

Mercedes Fernandez – Customer Service

Mackenzie Schneider – Order Fulfillment

Camryn Crist – Order Fulfillment

Gregory Harris – Customer Relations

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "GERYON HOLDINGS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF DECEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "GERYON HOLDINGS, LLC" WAS FORMED ON THE TWELFTH DAY OF SEPTEMBER, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



Jeffrey W. Bullock, Secretary of State

7022120 8300

SR# 20234255798

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204849068

Date: 12-18-23

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Geryon Holdings, LLC

Nevada Business Identification # NV20232720265
Expiration Date: 03/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 03/11/2024.

Certificate Number: B202403114454465
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State



Scott Kipper, Commissioner of Insurance

Resident Producer

Casualty, Property

BREANNA BOATRIGHT

50 W LIBERTY ST STE 920
RENO, NV 89501-1949

is authorized to transact business as described above

License No: 3609758 Issue Date: 11-17-2020 Expiration Date: 11-30-2026

Generated by Sircon 309921573

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

BREANNA BOATRIGHT
50 W LIBERTY ST STE 920, RENO, NV 89501-1949

LICENSE NUMBER: 3609758

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Resident Producer
Casualty, Property

Issue Date: 11-17-2020 Expiration Date: 11-30-2026

Generated by Sircon 309921573

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 7/31/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
InterWest Insurance Services, LLC
PO Box 8110
CHICO CA 95927

License#: 0B01094

CONTACT NAME: Julie Parker
PHONE (A/C, No, Ext): 5304912803 **FAX (A/C, No):** 5304912803
E-MAIL ADDRESS: jparker@iwins.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Sentinel Insurance Co Ltd	11000
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Geryon Holdings LLC
Sensis Invest USA, Inc.
10765 Double R Blvd Ste 200
Reno NV 89521

GERYHOL-01

COVERAGES **CERTIFICATE NUMBER:** 1227801235 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY	Y		57SBABO5012	7/24/2023	7/24/2024	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N	N / A		57WECAR8V5M	3/28/2023	3/28/2024	PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
This certificate is intended to provide evidence of the coverage in place on the date of issuance. It in no way amends, alters, or endorses that coverage.

CERTIFICATE HOLDER

Geryon Ventures LLC
Sensis Invest USA, Inc.
10765 Double R Blvd.
Suite 200
Reno NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Julie D. Parker

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The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100370859

Application/License No. _____

Geryon Holdings LLC dba DESS-USA (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 10765 Double R Blvd, Suite 200 Reno, NV 89521 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 1, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of March, 20 24.

APPLICANT/PRINCIPAL

COMPANY

Geryon Holdings LLC dba DESS-USA

Authorized Representative

SURETY

Merchants Bonding Company (Mutual)

Surety Company's Representative

Breanna Boatright, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent Breanna Boatright

LP 2079 NV (5/21)

Posted February 20, 2020

ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of Nevada
County of Washoe

On March 1, 2024 before me, Julie Heimdal, Notary Public
(insert name and title of the officer)

personally appeared Breanna Boatright,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and acknowledged to me that ~~he~~/she/~~they~~ executed the same in ~~his~~/her/~~their~~ authorized capacity(~~ies~~), and that by ~~his~~/her/~~their~~ signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

JULIE HEIMDAL
Notary Public
State of Nevada
Appt. No. 23-5258-02
My Appt. Expires Aug. 11, 2027

Signature _____ **(Seal)**

MERCHANTS BONDING COMPANY™

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Breanna Boatright

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 1st day of March , 2024

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 1st day of March , 2024 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA

Penni Miller
Commission Number 787952
My Commission Expires
January 20, 2027

Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 1st day of March , 2024 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

William Warner Jr.
Secretary

POA 0018 (1/24)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Geryon Holdings, LLC D/B/A DESS-USA — MDEG License # (if applicable): N/A
Physical Address: 10765 Double R Blvd., Suite 200
City: Reno — State: NV — Zip: 89521
Mailing Address (if different from physical address):
City: — State: — Zip:
Telephone: 855-337-7872 — Website: www.dess-usa.com
Licensing Company Email: darin.lockaby@dess-usa.com

Section 2: Personal Information

First: Curtis — Middle: Darin — Last: Lockaby
Alias(es, nicknames, name changes, etc.):
Date of Birt[redacted] — SSN or ITIN [redacted] — Sex: ☑ M ☐ F ☐ X
Mailing Address [redacted]
City: New Smyrna Beach — State: FL — Zip: 32169
Telephone [redacted] — Email [redacted]
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of North Georgia		08/87 -06/91	
Address	**City**	**State**	**Zip**
82 College Circle	Dahlonega	GA	30597
Diploma/Degree obtained, if any			
BBA - Accounting			

School Name		From - To (MM/YY – MM/YY)	
Troup County High School		08/84 - 06/87	
Address	**City**	**State**	**Zip**
1920 Hamilton Rd	Lagrange	GA	30241
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/21 - present	[redacted]	New Smyrna Beach	FL	32169
02/20 - 04/21		Orlando	FL	32825
12/99 - 02/20		Orlando	FL	32828
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Geryon Holdings, LLC D/B/A DESS-USA			09/23 - Present	
Business Address		**City**	**State**	**Zip**
10765 Double R Blvd, Ste 200		Reno	NV	89521
Phone	**Title**		**Number of Employed Hours**	
855-337-7872	President		440	
Description of Duties				
Responsible for overall business. Commercial, operations, IT, HR, and all other aspects of the day to day operations.				

Business Name			From - To (MM/YY – MM/YY)	
Kulzer North America			02/22 - 09/23	
Business Address		**City**	**State**	**Zip**
4315 S Lafayette Blvd		South Bend	IN	46614
Phone	**Title**		**Number of Employed Hours**	
574-291-0661	VP Sales		3200	
Description of Duties				
Responsible for commercial sales team and activities for North America for $85M in dental consumables				

Business Name			From - To (MM/YY – MM/YY)	
DentsplySirona			4/10 - 2/22	
Business Address		**City**	**State**	**Zip**
13320-B Ballantyne Corporate Place		Charlotte	NC	28277
Phone	**Title**		**Number of Employed Hours**	
704-587-0453	Director of Sales		22780	
Description of Duties				
Responsible for commercial sales of dental consumables and equipment for $200M				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Curtis Darin Lockaby, **certify that as the MDEG Administrator for**

Geryon Holdings, LLC D/B/A DESS-USA,

that I (initial that you have read and meet the following requirements):

1. CDL Have a high school diploma or its equivalent;
2. CDL Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CDL Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CDL Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lockaby, Curtis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/15/23

Date

Board Use Only	Date Received: 11/25/24

Geryon Holdings, LLC D/B/A DESS-USA
Attachment to Nevada State Board of Pharmacy
Designated Representative Application

I am the Chief Executive Officer of Geryon Holdings, LLC. I reside in Florida, but commute to work in Reno, Nevada for work, and am actively involved in and aware of the actual daily operations of the wholesaler, Geryon Holdings, LLC; am employed full time in a managerial-level position; and am physically present on site when I am not traveling on company business visiting customers, on vacation, or on sick leave.

I do not serve as the designated representative for any other Nevada pharmacy or wholesaler.

Respectfully submitted,



4/27/24

Curtis Darin Lockaby — Date Signed

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Geryon Holdings, LLC D/B/A DESS-USA
Pharmacy/Wholesaler License # (if applicable): N/A
Physical Address: 10765 Double R Blvd., Suite 200
City: Reno State: NV Zip: 89521
Mailing Address (if different from physical address):
City: State: Zip:
Telephone: 855-337-7872 Website: www.dess-usa.com
Licensing Company Email: darin.lockaby@dess-usa.com

Section 2: Personal Information

First: Curtis Middle: Darin Last: Lockaby
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X
Mailing Address: [redacted]
City: New Smyrna Beach State: FL Zip: 32169
Telephone: [redacted] Email: [redacted]
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
University of North Georgia			08/87 - 06/91
Address	**City**	**State**	**Zip**
82 College Circle	Dahlonega	GA	30597
Diploma/Degree obtained, if any			
BBA - Accounting			

School Name			From - To (MM/YY – MM/YY)
Troup County High School			08/84 - 06/87
Address	**City**	**State**	**Zip**
1920 Hamilton Rd	Lagrange	GA	30241
Diploma/Degree obtained, if any			
HS Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/21 - present	[redacted]	New Smyrna Beach	FL	32169
02/20 - 04/21		Orlando	FL	32825
12/99 - 02/20		Orlando	FL	32828
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Geryon Holdings, LLC D/B/A DESS-USA			9/23 - Present	
Business Address		**City**	**State**	**Zip**
10765 Double R Blvd, Ste 200		Reno	NV	89521
Phone	**Title**		**Number of Employed Hours**	
855-337-7872	President		440	
Description of Duties				
Responsible for overall business. Commercial, operations, IT, HR, and all other aspects of the day to day operations.				

Business Name			From - To (MM/YY – MM/YY)	
Kulzer North America			2/22 - 9/23	
Business Address		**City**	**State**	**Zip**
4315 S Lafayette Blvd		South Bend	IN	46614
Phone	**Title**		**Number of Employed Hours**	
574-291-0661	VP Sales		3200	
Description of Duties				
Responsible for commercial sales team and activities for North America for $85M in dental consumables.				

Business Name			From - To (MM/YY – MM/YY)	
DentsplySirona			4/10 - 2/22	
Business Address		**City**	**State**	**Zip**
13320-B Ballantyne Corporate Place		Charlotte	NC	28277
Phone	**Title**		**Number of Employed Hours**	
704-587-0453	Director of Sales		22780	
Description of Duties				
Responsible for commercial sales of dental consumables and equipment for $200M				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/15/23
Date

I, Curtis Darin Lockaby, **certify that as the designated representative for**

Geryon Holdings, LLC D/B/A DESS-USA,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CDL I am at least 21 years of age;
3. CDL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CDL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CDL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CDL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CDL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lockaby, Curtis

Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

11/15/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Curtis D. Lockey

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/15/23

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Curtis D. Lockey, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/15/23

Date

Subscribed and Sworn to before me this 15th day of November.

Katie Wendel

Notary Public Signature

KATIE WENDEL
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 21-6837-02
My Appt. Expires MARCH 17, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Geryon Holdings, LLC D/B/A DESS

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 10765 Double R Blvd., Suite 200

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-337-7872 Website: www.dess-usa.com

Licensing Company Email: [redacted]@gmail.com

Section 2: Personal Information

First: Curtis Middle: Davin Last: Lockaby

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: New Smyrna Beach State: FL Zip: 32169

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of North Georgia		9/87 - 5/91	
Address	City	State	Zip
	Dahlonega	GA	
Diploma/Degree obtained, if any			
BBA - Accounting			

School Name		From - To (MM/YY – MM/YY)	
Troup County High School		9/83 - 5/87	
Address	City	State	Zip
	LaGrange	GA	30241
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/21 - present	[redacted]	New Smyrna Beach	FL	32169
2/19 - 5/21		Orlando	FL	32825
12/97 - 2/19		Orlando	FL	32825
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Kaiser North America			2/22 – 9/23
Business Address	**City**	**State**	**Zip**
4315 S Lafayette Blvd	South Bend	IN	46614
Phone	**Title**		
574-291-0661	Vice President Sales		
Description of Duties			
Manage sales force for North America			

Business Name			From - To (MM/YY – MM/YY)
Dentsply Sirona			4/10 – 2/22
Business Address	**City**	**State**	**Zip**
13320-B Ballantyne Corporate Place	Charlotte	NC	28277
Phone	**Title**		
704-587-0453	Director of Sales		
Description of Duties			
Led sales team for Southeast USA			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Curtis D. Lochy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/21/23

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Curtis D. Lochy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/21/23

Date

Subscribed and Sworn to before me this 21st day of September

Katie Wendell

Notary Public Signature

KATIE WENDEL
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 21-6837-02
My Appt. Expires MARCH 17, 2025

(Seal)

N31666

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Geryon Holdings, LLC D/B/A DESS

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 10765 Double R Blvd., Suite 200

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-337-7872 Website: www.dess-usa.com

Licensing Company Email: darin.lockaby@dess-usa.com

Section 2: Personal Information

First: Roger Middle: Last: Terrats Bes

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITIN: None-foreign Sex: ☒ M ☐ F ☐ X

Mailing Addres[redacted]

City: Barcelona State: SPAIN Zip: 08006

Telephone[redacted] Ema[redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Universitat Politècnica de Catalunya		(09/97-06/00)	
Address	**City**	**State**	**Zip**
Carrer de Jordi Girona, 31	Barcelona	Spain	08034
Diploma/Degree obtained, if any			
Electronic Master Engineering			

School Name		From - To (MM/YY – MM/YY)	
Universitat Ramon Llull, Escola La Salle		(09/91-06/97)	
Address	**City**	**State**	**Zip**
C. dels Quatre Camins, 60	Barcelona	Spain	08022
Diploma/Degree obtained, if any			
Telecom Engineering			

School Name		From - To (MM/YY – MM/YY)	
Jesuïtes de Sarrià (Escola Sant Ignasi)		(09/87-06/91)	
Address	**City**	**State**	**Zip**
Carrasco i Formiguera 32	Barcelona	Spain	08017
Diploma/Degree obtained, if any			
BUP i COU			

School Name		From - To (MM/YY – MM/YY)	
Sant Antoni Maria Claret		(09/79-06/87)	
Address	**City**	**State**	**Zip**
Sant Antoni Maria Clare 49	Barcelona	Spain	08025
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
(10/21 - 11/23)	[redacted]	Barcelona	Spain	08006
(10/13 - 09/21)		Barcelona	Spain	08024

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Terrats Medical, S.L.			(01/09-11/23)	
Business Address		**City**	**State**	**Zip**
Mogoda 75-99		Barbera del Valles	Spain	08210
Phone	**Title**			
+34935646006	Chief Execuive Officer			

Description of Duties

As CEO, he is the highest ranking of company so he's maximum responsible of strategic direction of company, interacting with leadership executives and with the board and the rest of shareholders.

Business Name			From - To (MM/YY – MM/YY)	
Sensis Invest, S.L.			(10/20-11/23)	
Business Address		**City**	**State**	**Zip**
Mogoda 75-99		Barbera del Valles	Spain	08210
Phone	**Title**			
+34935646006	Chief Executive Officer			

Description of Duties

As CEO, he is the highest ranking of company so he's maximum responsible of strategic direction of company, interacting with leadership executives and with the board and the rest of shareholders.

Business Name			From - To (MM/YY – MM/YY)	
Sensis Invest USA Inc			(10/22 - 11/23)	
Business Address		**City**	**State**	**Zip**
10765 Double R Blvd., Suite 200		Reno	NV	89521
Phone	**Title**			
855-337-7872	Chief Executive Officer			

Description of Duties

Sensis Invest USA Inc is a holding company created for Geryon acquisition purposes. As CEO, he is responsible for all aspects of its operation.

Business Name			From - To (MM/YY – MM/YY)	
Geryon Holdings, LLC			(06/23 - 11/23)	
Business Address		**City**	**State**	**Zip**
10765 Double R Blvd., Suite 200		Reno	NV	89521
Phone	**Title**			
855-337-7872	Chief Executive Officer			

Description of Duties

As CEO, he is the highest ranking of company so he's maximum responsible of strategic direction of company, interacting with leadership executives and with the board and the rest of shareholders.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

12/12/2023
Date

Yo, RAMÓN GARCÍA-TORRENT CARBALLO, Notario del Ilustre Colegio Notarial de Catalunya, con residencia en Barcelona, DOY FE: Que, por haber sido puesta a mi presencia, reputo como legítima y auténtica la firma y rúbrica que antecede de Don Roger Terrats Bes, titular del DNI número 38.130.894-E. ----------

Anotado en mi Libro Indicador del año 2023 (sección segunda) Asiento: 1804 Barcelona, a 13 de diciembre de dos mil veintitrés. ----------

I, RAMÓN GARCÍA-TORRENT CARBALLO, Public Notary of Barcelona, Kingdom of Spain, hereby certify the presentation of the present document, having signed in front of me Mr. Roger Terrats Bes, holder of Spanish identity card number 38.130.894-E. ----------

Noted down under number 1804 of my register book of the present year. - Barcelona, 13th of December of 2023. ----------

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roger Terrats-Bes

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/12/2023

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, ROGER TERRATS-BES, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/12/2023

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

01/2023

HJ0101559

El presente folio es el agregado al documento en el que figura la firma de Don Ramón García-Torrent Carballo, Notario de Barcelona, Colegio Notarial de Cataluña, en legitimación de firma de don Roger Terrats Bes, en documento en relación a TERRATS MEDICAL, S.L., libro indicador 1804, de 13 de diciembre de 2023.

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. **País:** ESPAÑA
   Country / Pays :

El presente documento público
This public document / Le présent acte public

2. **ha sido firmado por** Don Ramón García-Torrent Carballo
   has been signed by
   a été signé par

3. **quien actúa en calidad de** NOTARIO
   acting in the capacity of
   agissant en qualité de

4. **y está revestido del sello / timbre de** la Notaría
   bears the seal / stamp of
   est revêtu du sceau / timbre de

Certificado
Certified / Attesté

5. **en** Barcelona at / à	6. **el día** 13/12/2023 the / le

7. **por** Don Javier Martínez Lehmann, Notario Delegado del Decano del Colegio Notarial de Cataluña
   by / par

8. **bajo el número** N5301/2023/067477
   No
   sous no

9. **Sello / timbre:**
   Seal / stamp:
   Sceau / timbre:

FE PÚBLICA NOTARIAL
CONSEJO GENERAL DEL NOTARIADO ESPAÑOL
NOTARIADO EUROPA
NIHIL PRIUS FIDE
A012521234
0288363808

10. **Firma:**
    Signature:
    Signature :

Javier Martínez Lehmann, Delegado del Decano

Esta Apostilla certifica únicamente la autenticidad de la firma, la calidad en que el signatario del documento haya actuado y, en su caso, la identidad del sello o timbre del que el documento público esté revestido.

Esta Apostilla no certifica el contenido del documento para el cual se expidió.

[No es válido el uso de esta Apostilla en España]

[Esta Apostilla se puede verificar en la dirección siguiente: https://eregister.justicia.es/]

Código de verificación de la Apostilla: NA:r0j+-Jrkn-RR1e-oBgy

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This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.

This Apostille does not certify the content of the document for which it was issued.

[This Apostille is not valid for use anywhere within Spain]

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Verification Code of the Apostille: NA:r0j+-Jrkn-RR1e-oBgy

Cette Apostille atteste uniquement la véracité de la signature, la qualité en laquelle le signataire de l'acte a agi et, le cas échéant, l'identité du sceau ou timbre dont cet acte public est revêtu.

Cette Apostille ne certifie pas le contenu de l'acte pour lequel elle a été émise.

[L'utilisation de cette Apostille n'est pas valable en / au Espagne.]

[Cette Apostille peut être vérifiée à l'adresse suivante https://eregister.justicia.es/]

Code de verification de l'Apostille: NA:r0j+-Jrkn-RR1e-oBgy

N32951 4

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Geryon Holdings, LLC D/B/A DESS

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 10765 Double R Blvd., Suite 200

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-337-7872 Website: www.dess-usa.com

Licensing Company Email: [redacted]@gmail.com

Section 2: Personal Information

First: Ramon Middle: Last: Terrats Bes

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: None-foreign Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Sant Quirze del Valles State: SPAIN Zip: 08192

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ■ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

HOJA 1/4

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
JESUÏTES El CLOT		09/95 - 06/99)	
Address	**City**	**State**	**Zip**
Carrer València, 680	Barcelona	Spain	08207
Diploma/Degree obtained, if any			
FP2 INDUSTRIAL MECHANIC			

School Name		From - To (MM/YY – MM/YY)	
C.P.VILLAR		(09/93 - 06/95)	
Address	**City**	**State**	**Zip**
Carrer de Sant Salvador, 29	Barcelona	Spain	08212
Diploma/Degree obtained, if any			
FP1 ELECTRONIC			

School Name		From - To (MM/YY – MM/YY)	
El Patufet		(09/91- 07/93)	
Address	**City**	**State**	**Zip**
Carrer de Bruniquer, 25	Barcelona	Spain	08012
Diploma/Degree obtained, if any			
CES			

School Name		From - To (MM/YY – MM/YY)	
COL-LEGI CLARET BARCELONA		(09/85 - 07/91	
Address	**City**	**State**	**Zip**
Sant Antoni Maria Claret 49	Barcelona	Spain	08025
Diploma/Degree obtained, if any			
EGB			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
(12/19 - 12/23)	[redacted]	Sant Quirze Del Valles	Spain	08192
(09/04 - 12/19)		Sant Quirze Del Valles	Spain	08192

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Terrats Medical, S.L.			12/21 - 12/23
Business Address	**City**	**State**	**Zip**
Mogoda 75-99	Barbera del Valles	Spain	08210
Phone	**Title**		
+34935646006	Project Officer		

Description of Duties

Executive position that manages the planning and detail special projects. Manage the proper development of products and services. Design projects and follows up the planning established and agreed with the CTO.

Business Name			From - To (MM/YY – MM/YY)
Terrats Medical, S.L.			10/13 - 12/21
Business Address	**City**	**State**	**Zip**
Mogoda 75-99	Barbera del Valles	Spain	08210
Phone	**Title**		
+34935646006	Chief Technical Officer		

Description of Duties

Management position led by the Dtp. Engineering and technical strategy within the company. Develop policies and procedures and use technologies to improve products and services to external customers.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

HOJA 2/4

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

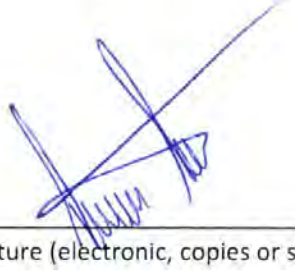
HOJA 3/4

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

28/12/2023
(12/28/2023)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RAMON TERRATS BES

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

28/12/2023

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, RAMON TERRATS BES, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

28/12/2023

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

HOJA 4/4

Yo, RAMÓN GARCÍA-TORRENT CARBALLO, Notario del Ilustre Colegio Notarial de Catalunya, con residencia en Barcelona, DOY FE: Que, por haber sido puesta a mi presencia, reputo como legítima y auténtica la firma y rúbrica que antecede de Don Ramon Terrats Bes, titular del DNI número 36.531.220-K. ----------

Anotado en mi Libro Indicador del año 2023 (sección segunda) Asiento: 1889 Barcelona, a 28 de diciembre de dos mil veintitrés. ----------

I, RAMÓN GARCÍA-TORRENT CARBALLO, Public Notary of Barcelona, Kingdom of Spain, hereby certify the presentation of the present document, having signed in front of me Mr. Ramon Terrats Bes, holder of Spanish identity card number 36.531.220-K. ----------

Noted down under number 1889 of my register book of the present year. - Barcelona, 28th of December of 2023. ----------

PAPEL EXCLUSIVO PARA DOCUMENTOS NOTARIALES

TIMBRE DEL ESTADO

01/2023

0,15 €

HJ0128836

El presente folio es el agregado al documento en el que figura la firma de Don Ramón García-Torrent Carballo, Notario de Barcelona, Colegio Notarial de Cataluña, en legitimación de firma de don Ramon Terrats Bes, en documento de solicitud de historial personal, a nombre de GERYON HOLDINGS, LLC, libro indicador 1889, de 28 de diciembre de 2023.

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. **País:** ESPAÑA
   Country / Pays :

El presente documento público
This public document / Le présent acte public

2. **ha sido firmado por** Don Ramón García-Torrent Carballo
   has been signed by
   a été signé par

3. **quien actúa en calidad de** NOTARIO
   acting in the capacity of
   agissant en qualité de

4. **y está revestido del sello / timbre de** la Notaría
   bears the seal / stamp of
   est revêtu du sceau / timbre de

Certificado
Certified / Attesté

5. **en** Barcelona at / à	6. **el día** 29/12/2023 the / le

7. **por** Don José Marqueño Ellacuría, Censor Primero del Colegio Notarial de Cataluña
   by / par

8. **bajo el número** N5301/2023/070497
   No
   sous no

9. **Sello / timbre:** Seal / stamp: Sceau / timbre:	10. **Firma:** Signature: Signature :

FE PÚBLICA NOTARIAL
CONSEJO GENERAL DEL NOTARIADO ESPAÑOL
NOTARIADO EUROPA
NIHIL PRIUS FIDE
A16521323
0290922098

José Marqueño Ellacuría, Censor Primero

Esta Apostilla certifica únicamente la autenticidad de la firma, la calidad en que el signatario del documento haya actuado y, en su caso, la identidad del sello o timbre del que el documento público esté revestido.

Esta Apostilla no certifica el contenido del documento para el cual se expidió.

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Code de verification de l'Apostille:NA:XYa7-GWWr-npTE-Nhqh

N32951

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Geryon Holdings, LLC D/B/A DESS

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 10765 Double R Blvd., Suite 200

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-337-7872 Website: www.dess-usa.com

Licensing Company Email: [redacted]@gmail.com

Section 2: Personal Information

First: Jordi Middle: Last: Terrats Bes

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: None-foreign Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Barcelona State: SPAIN Zip: 08022

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ■ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

HOJA 1/4

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Escola Tècnica Professional del Clot		(07/94 - 09/95)	
Address	City	State	Zip
València, 680	Barcelona	Spain	08027
Diploma/Degree obtained, if any			
FP-II Industrial Mechanics			
School Name		From - To (MM/YY – MM/YY)	
Escola Tècnica Professional del Clot		(07/92 - 09/94)	
Address	City	State	Zip
València, 680	Barcelona	Spain	08027
Diploma/Degree obtained, if any			
FP-II Industrial Electronics			
School Name		From - To (MM/YY – MM/YY)	
Escola Sant Ignasi		(09/90 - 07/92)	
Address	City	State	Zip
Carrasco i Formiguera, 32	Barcelona	Spain	08017
Diploma/Degree obtained, if any			
CES			
School Name		From - To (MM/YY – MM/YY)	
COL-LEGI CLARET BARCELONA		(09/82 - 07/90)	
Address	City	State	Zip
Sant Antoni Maria Claret 49	Barcelona	Spain	08025
Diploma/Degree obtained, if any			
EGB			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
(12/20 - 12/23)	[redacted]	Barcelona	Spain	08041
From - To (MM/YY – MM/YY)		City	State	Zip
(01/112 - 11/20)		Barcelona	Spain	08026
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Terrats Medical, S.L.			01/95-12/23
Business Address	**City**	**State**	**Zip**
Mogoda 75-99	Barbera del Valles	Spain	08210
Phone	**Title**		
+34935646006	Chief Production Officer		

Description of Duties

The CPO is a strategic leader, visionary, team supervisor, and an advocate of an organization's product. In charge of the creation and definition of products/service, liaising closely with R+D department to turn technology into products.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

HOJA 2/4

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

HOJA 3/4

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

28-12-2023

Date (12/28/2023)

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jordi Terrats Boy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

28-12-2023

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Jordi Terrats Boy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

28-12-2023

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

HOJA 4/4

Yo, RAMÓN GARCÍA-TORRENT CARBALLO, Notario del Ilustre Colegio Notarial de Catalunya, con residencia en Barcelona, DOY FE: Que, por haber sido puesta a mi presencia, reputo como legítima y auténtica la firma y rúbrica que antecede de Don Jordi Terrats Bes, titular del DNI número 36.531.221-E. ----------
Anotado en mi Libro Indicador del año 2023 (sección segunda) Asiento: 1891
Barcelona, a 28 de diciembre de dos mil veintitrés. ----------

I, RAMÓN GARCÍA-TORRENT CARBALLO, Public Notary of Barcelona, Kingdom of Spain, hereby certify the presentation of the present document, having signed in front of me Mr. Jordi Terrats Bes, holder of Spanish identity card number 36.531.221-E. ----------
Noted down under number 1891 of my register book of the present year. -
Barcelona, 28th of December of 2023. ----------

PAPEL EXCLUSIVO PARA DOCUMENTOS NOTARIALES

TIMBRE DEL ESTADO

01/2023

0,15 €

HJ0128835

El presente folio es el agregado al documento en el que figura la firma de Don Ramón García-Torrent Carballo, Notario de Barcelona, Colegio Notarial de Cataluña, en legitimación de firma de don Jordi Terrats Bes, en documento de solicitud de historial personal, a nombre de GERYON HOLDINGS, LLC, libro indicador 1891, de 28 de diciembre de 2023.

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. **País:** ESPAÑA
   Country / Pays :

El presente documento público
This public document / Le présent acte public

2. **ha sido firmado por** Don Ramón García-Torrent Carballo
   has been signed by
   a été signé par

3. **quien actúa en calidad de** NOTARIO
   acting in the capacity of
   agissant en qualité de

4. **y está revestido del sello / timbre de** la Notaría
   bears the seal / stamp of
   est revêtu du sceau / timbre de

Certificado
Certified / Attesté

5. **en** Barcelona at / à	6. **el día** 29/12/2023 the / le
7. **por** Don José Marqueño Ellacuría, Censor Primero del Colegio Notarial de Cataluña by / par	
8. **bajo el número** N5301/2023/070498 No sous no	
9. **Sello / timbre:** Seal / stamp: Sceau / timbre:	10. **Firma:** Signature: Signature :

FE PÚBLICA NOTARIAL
CONSEJO GENERAL NOTARIADO EUROPA NIHIL PRIUS FIDE
NOTARIADO ESPAÑOL
A24521323
0290922099

José Marqueño Ellacuría, Censor Primero

Esta Apostilla certifica únicamente la autenticidad de la firma, la calidad en que el signatario del documento haya actuado y, en su caso, la identidad del sello o timbre del que el documento público esté revestido.

Esta Apostilla no certifica el contenido del documento para el cual se expidió.

[No es válido el uso de esta Apostilla en España]

[Esta Apostilla se puede verificar en la dirección siguiente: https://eregister.justicia.es/]

Código de verificación de la Apostilla: NA:UTtx-BTbR-/76M-UL+8

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.

This Apostille does not certify the content of the document for which it was issued.

[This Apostille is not valid for use anywhere within Spain]

[To verify the issuance of this Apostille, see https://eregister.justicia.es/]

Verification Code of the Apostille:NA:UTtx-BTbR-/76M-UL+8

Cette Apostille atteste uniquement la véracité de la signature, la qualité en laquelle le signataire de l'acte a agi et, le cas échéant, l'identité du sceau ou timbre dont cet acte public est revêtu.

Cette Apostille ne certifie pas le contenu de l'acte pour lequel elle a été émise.

[L'utilisation de cette Apostille n'est pas valable en / au Espagne.]

[Cette Apostille peut être vérifiée à l'adresse suivante https://eregister.justicia.es/]

Code de verification de l'Apostille:NA:UTtx-BTbR-/76M-UL+8

14

14A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR NEVADA WAREHOUSE LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Warehouse ☐ Ownership Change ☐ Name Change ☐ Location Change
(Please provide current license number if making changes: WA _____)

☒ Publicly Traded Corporation – Page 1,2,3,4 ☐ Partnership - Page 1,2,3,6,6a
☐ Non Publicly Traded Corporation – Page 1,2,3,5,5a,5b ☐ Sole Owner – Page 1,2,3,7,7a
Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION

Facility Name: Eyenovia, Inc.

Physical Address: 9736 South Virginia Street, Suite F & G

Mailing Address: 9736 South Virginia Street, Suite F & G

City: Reno State: NV Zip Code: 89511

Telephone: 833-393-6684 Fax: _____

Toll Free Number: 833-393-6684

E-mail: KRodgers@eyenovia.com Website: www.eyenovia.com

Facility Manager: Kristian Rodgers

Professional qualifications and experience of facility manager: Please see attached resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☒ Manufacturer ☐ Chain Warehouse ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled be firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR NEVADA WAREHOUSE LICENSE

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

1) N/A
Name Address
Business

2)
Name Address
Business

3)
Name Address
Business

4)
Name Address
Business

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

APPLICATION FOR NEVADA WAREHOUSE LICENSE

This page must be submitted for all types of ownership.

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized warehouse may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael Rowe, CEO
Print Name of Authorized Person

6-19-2024
Date

Board Use Only	Received: 6/24/24	Amount: $500 ck 1039

APPLICATION FOR NEVADA WAREHOUSE LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: _____

Corporation Name: Eyenovia, Inc

Mailing Address: 295 Madison Ave Suite 2400

City: New York State: NY Zip: 10017

Telephone: 833-393-6684 Fax: _____

Contact Person: Eric Trosko

Ownership Information – Complete Section 1 or 2

Do not use N/A in this section – Section 1 or 2 must be completed.

Section 1: List the corporations four largest shareholders:
(Name and percentage of ownership)

1. Stuart Grant %: 10.66%
2. Armistice Capital, LLC %: 8.59%
3. Tsontcho Ianchulev %: 1.89%
4. Ellen Strahlman %: 0.15%

Section 2: If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

*Date of Incorporation: _____

*Registration number issued: _____

*Stock Exchange: _____

Include with the application for a publicly traded corporation

List of officers and directors.

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

Eyenovia Corporate Officers

Name	Street	City	State	Zip Code
Michael Rowe, CEO	[redacted]S. Pointe Drive Suite 390	Laguna Hills	CA	92653
John Gandolfo, CFO	[redacted]Madison Ave Suite 2400	New York	NY	10017
Bren Kern, COO	[redacted]Haven Ave	Redwood City	CA	94063

Eyenovia Board of Directors

Name	Position
Sean Ianchulev, MD	Chairman of the Board
Charles Mather	Independent Director
Rachel Jacobson	Independent Director
Ellen Strahlman, MD	Independent Director
Ram Palanki, PharmD	Independent Director
Michael Geltzeiler	Independent Director
Michael Rowe	Director

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "EYENOVIA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF JANUARY, A.D. 2024.

Jeffrey W. Bullock, Secretary of State

5573930 8300

SR# 20234259834

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202584575

Date: 01-12-24

KRIS RODGERS

Professional Summary

Results-oriented supply chain professional with an accomplished work history and performance record. A proven leader with excellent communications skills and an ability to work with individuals at all levels to drive results. Self-motivated, possessing a high degree of integrity, an outstanding work ethic, and a demonstrated ability to thrive in dynamic, challenging, fast-paced environments.

Professional Experience

General Manager / Sr. Supply Chain Manager / Sr. Buyer 01/2020 to present
Eyenovia, Inc. Reno, Nevada

- Ensured availability of materials (components, sub-assemblies, finished goods) and aligned appropriate inventory levels to meet business demand.
- Identified supplier requirements and communicated expectations to Eyenovia stakeholders, while conducting supplier assessments for production capacity, conformance, and quality.
- Led initiative to expand and improve the use of a company ERP system (Cetec). Developed company standard operating procedures relating to procurement, inventory management, as well as work instructions for ERP processes.
- Developed company demand and capacity tracking and led cross functional meeting to communicate the schedule and plan.
- Promoted to Sr. Supply Chain Manager 10/04/2021
- Promoted to General Manager 11/15/2022.

Sr. Buyer 10/2017 to 08/2019
Zazzle Inc. Reno, Nevada

- Responsible for purchasing, distribution, and inventory control to support e-commerce manufacturing network for customized printing.
- Successfully developed several Kaizens / cost reduction projects, helping to save the company over $100k per year.
- Initiated vendor inventory consignment programs to reduce expenses while improving product availability, driving On Time Performance from <90% to >98%.
- Implemented systematic cycle count program resulting in 5-10% increase in inventory accuracy and reduced inventory adjustments by 19% YtY.
- "CHIA" award recipient Q3 2019.

General Manager - West Coast Distribution Center 02/2012 to 06/2017

KRIS RODGERS

[redacted]Caballo Drive Reno, NV. 89502 | [redacted]

EndoChoice Inc. Reno, Nevada

- Provided the overall leadership and patient-focused vision for a medical kit manufacturing and distribution facility, supporting more than 500,000 medical procedures each year.
- Achieved > 99.8% On-Time Delivery and Zero reported customer "NCMR's" for 3 straight years.
- Improved associate productivity and reduced operating costs by implementing a "Pay for Performance" incentive program for associates.
- Recipient of the "Founders Award" in 2014 and "C.H.I.E." Award in 2015.
- "Lean Leader" 2014-2016.

Director of Logistics 04/2006 to 11/2011
BriteVision Media LLC Reno, Nevada

- Responsible for ensuring efficient material purchase and product delivery to meet production schedule and customer delivery demands for high volume "Coffee Sleeve" manufacturing and distribution facility.
- Created a more agile supply chain resulting in smaller, more frequent production runs and faster product delivery reducing the overall product "time to market" from 6 weeks to 2 weeks.
- Reduced manufacturing and supply chain expenses, reducing the overall "cost per unit" from $.08 to $.05.
- Leader of various Lean / 5S projects that reduced downtime and changeovers on the production equipment, as well as reduced plant waste and improved company recycling efforts.

Facility Manager / Operations Manager 01/2002 to 01/2006
Ozburn-Hessey Logistics Nashville, TN

- Managed the inventory control, fulfillment, shipping/receiving, and general warehousing and logistics operations' of more than 30 various 3rd party accounts including Amazon and Starbucks.
- Successfully led a training program for new Operations Supervisors.
- Relocated to Nashville TN. and directed a 3-shift operation serving over 3300+ Starbucks retailers at a 99.9% fill rate.
- Achieved 99.98% On-Time delivery during first 12 months in operation.
- Starbucks' "Bravo Bean" Partner of the Year Award, 2002 and 2004.

KRIS RODGERS

[redacted]Caballo Drive Reno, NV. 89502 | [redacted]

Administrative Services Supervisor / Logistics Intern 10/1997 to 01/2002
State Farm Insurance Co. Reno, Nevada

- Successfully managed the supply needs of over 25,000 State Farm Agents and associates in 13 Western States.
- Directed a "product cube and slotting" analysis to evaluate and recommend product locations, improving overall operational efficiency and safety.
- Improved the Reverse Logistics process which resulted in a quicker process to credit Agents' returns.
- Successfully completed State Farm's Internship, Supervisory Development Curriculum, and Management Development Programs.

Skills Highlights

- Leadership
- Supply Chain Management
- Production Scheduling / Planning
- Inventory Management
- Training and Development
- Lean / Six Sigma Certification
- Continuous Improvement
- Process Design / Implementation
- Vendor Management
- P&L's, Cap. Exp., Budgeting

Education

Bachelor of Science | Logistics Management | University of Nevada

Green Belt Certification | Lean / Six Sigma | University of Nevada

Mark I. Sedar

From: Lilian Ofulue-Eze <LOfulue-Eze@eyenovia.com>
Sent: Thursday, June 20, 2024 1:04 PM
To: Mark I. Sedar
Cc: Leo D. Basch; Bill Daly
Subject: Re: Is License Required?
Attachments: Nevada State Board of Pharmacy $500_06.19.24.pdf; Nevada_Application for Nevada Warehouse License 2024.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello Mark,

We have sent the completed application and the corresponding check overnight (See attached documents). I wonder if you can get us on the schedule with the Board in July? We are running out of storage space at our Redwood City, CA facility.

Regards,

Lilian Ofulue-Eze | Director of Quality /DRIC
LOfulue-Eze@eyenovia.com
www.eyenovia.com
OOO 06-21-24

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Tuesday, June 18, 2024 13:03
To: Lilian Ofulue-Eze <LOfulue-Eze@eyenovia.com>
Cc: Leo D. Basch <lbasch@pharmacy.nv.gov>; Bill Daly <bdaly@eyenovia.com>
Subject: RE: Is License Required?

Hi Lilian,

Please find the attached application.

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

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From: Lilian Ofulue-Eze <LOfulue-Eze@eyenovia.com>
Sent: Tuesday, June 18, 2024 12:17 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Cc: Leo D. Basch <lbasch@pharmacy.nv.gov>; Bill Daly <bdaly@eyenovia.com>
Subject: Re: Is License Required?

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello Mark,

We have decided to pursue a warehouse license to store our drug products so I was wondering if you could share the link to the application.

Regards,

Lilian Ofulue-Eze | Director of Quality /DRIC
LOfulue-Eze@eyenovia.com
www.eyenovia.com
OOO 06-21-24

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Monday, June 10, 2024 09:26
To: Lilian Ofulue-Eze <LOfulue-Eze@eyenovia.com>
Cc: Leo D. Basch <lbasch@pharmacy.nv.gov>
Subject: RE: Is License Required?

Good morning Lilian,

Thank you for your email. To expand on your questions, does the facility currently hold a license with our board? If this is for a new location in Reno, please refer to the following statutes and regulations listed below.

NRS 639.233 License required.

1. Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of this chapter.

2. For the purpose of this section, a person is "engaged in the business of furnishing" if the person:

(a) Solicits or accepts orders for drugs or devices whose sale in this State is restricted by this chapter or chapter 453 or 454 of NRS; or

(b) Receives, stores or ships such drugs or devices.

(Added to NRS by 1967, 1657; A 1971, 2041; 1973, 780; 1979, 1693; 1991, 1160; 1993, 1222; 2003, 2288)

NAC 639.622 "Authorized warehouse" defined. (NRS 639.070) "Authorized warehouse" means a warehouse or other business in this State that receives, stores or ships prescription drugs and goods pursuant to a written contract with a manufacturer, wholesaler, pharmacy or chain warehouse under which the authorized warehouse acts solely as the agent or bailee of the manufacturer, wholesaler, pharmacy or chain warehouse. The term includes a third-party logistics provider.

(Added to NAC by Bd. of Pharmacy, eff. 10-1-93; A by R218-05, 5-4-2006)

NAC 639.6935 "Medical products" defined. (NRS 639.070)

1. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease.

2. The term does not include:

(a) Controlled substances;

(b) Dangerous drugs, except medical gases and supplies that facilitate the use of a dangerous drug, including, without limitation, normal saline and other similar inert liquids;

(c) Medical devices, equipment, supplies or gases the regulation of which is governed by any other board or agency other than the Board; and

(d) Pressurized stockings that have a pressure rating of less than 20 millimeters of mercury.

(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001; A by R033-07, 8-26-2008)

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

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applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Leo D. Basch <lbasch@pharmacy.nv.gov>
Sent: Friday, June 7, 2024 6:49 AM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Cc: LOfulue-Eze@eyenovia.com
Subject: FW: Is License Required?

Hello Mr Sedar,
Please see license question below.

Thanks,

Leo Basch, Pharm D
Inspector

Nevada State Board of Pharmacy
1140 N Town Center Drive, Ste 300
Las Vegas, NV, 89144

Office: 702.486.6420 ext 155
Fax: 702.486.7903
E-mail: LBasch@pharmacy.nv.gov
Web Page: www.bop.nv.gov

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From: Lilian Ofulue-Eze <LOfulue-Eze@eyenovia.com>
Sent: Wednesday, June 5, 2024 2:41 PM
To: Pharmacy Board <pharmacy@pharmacy.nv.gov>; Leo D. Basch <lbasch@pharmacy.nv.gov>
Subject: Is License Required?

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello Licensing Desk,

I am trying to determine if a permit with a supplemental application is needed for a Drug/Medical device manufacturer in Reno, NV that will only be doing the following activities:

Immediate Use:

- store drug product for non -commercial use (clinical/R&D)

Future Use:

- Store commercial drug product
- Package commercial drug product

Regards,

Lilian Ofulue-Eze | Site Quality Head /DRIC
LOfulue-Eze@eyenovia.com
www.eyenovia.com
OOO 06-21-24

15

15A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist Application
Non-Refundable $250 fee

Rev (06/28/2022)

Section 1: Select how will you be obtaining your Nevada Pharmacist Registration

☐ **Examination**

☐ **Score Transfer** (Transfer your NAPLEX SCORE to Nevada within 89 days after taking your exam at https://nabp.pharmacy/ before completing this application.)

☑ **Reciprocation** (Complete NABP's Electronic Licensure Transfer Program (e-LTP) application at https://nabp.pharmacy/ before completing this application.)

Are you submitting this application to RETAKE the NAPLEX and/or MPJE? ☐ Yes ☑ No

Section 2: General Information

First: Sean Middle: Patrick Last: Levins

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Westbend Dr

City: Dardenne Prairie State: MO Zip: 63368

Telephone: [redacted] Email: [redacted]

Section 3: Employment Information

Pharmacy Name: Optime Care NV Pharmacy License # (if applicable): PH03575

Address: 4060 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Telephone: 833-744-3562 Email: support@rigelonecare.com

Section 4: College of Pharmacy Information

School Name: University of Health and Sciences in St. Louis

Address: 1 Pharmacy Place

City: St. Louis State: MO Zip: 63110

Country/Territory/Province: USA

Graduation Date: 05/2010 Degree: ☑ PharmD ☐ BS in Pharmacy ☐ Other

Section 5: ONLY COMPLETE this section if you are applying for a Nevada Pharmacist Registration by RECIPROCATION.

Original State of licensure/registration you are reciprocating from must be active and issued by exam (passing the NAPLEX and that state's MPJE).

State: MO License #: 2010026504 Date of Issuance: 07/29/2010 Expiry Date: 10/31/2024

Section 6: List all pharmacist license/registration you have/had in other states. Use another sheet if additional space is needed.								
State	License/ Registration #	Issued Date	Expiry Date	License/Registration Status (check applicable box)				
				Active	Inactive	Expired	Revoked	Surrendered

Section 7: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 8: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 9: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?	✔	
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

STATE OF MISSOURI
DIVISION OF PROFESSIONAL REGISTRATION
MISSOURI BOARD OF PHARMACY

REQUEST FOR WRITTEN RESPONSE

CASE NUMBER	DATE
2023-003652	12/28/2023
PHARMACY	**PERMIT NUMBER**
Wal-Mart Pharmacy 10-1021	2002009460
PHARMACIST	**LICENSE NUMBER**
Sean Levins	2010026504

Your cooperation in providing information during this investigation is appreciated. On a separate sheet, provide a written response regarding the following investigation issues.

The Board office received notification of pharmacist discipline which resulted in the termination of your employment on 9/29/2023, from Wal-Mart Pharmacy 10-1021, 500 Warren County Center, Warrenton, MO, for reasons of gross misconduct resulting from an internal investigation by Wal-Mart.

Board investigation of the incidents which occurred at your place of residence, with a 19 year old male pharmacy technician, "LL", over a period between July, 2022, to September, 2022, revealed the allegations by the technician that you, Sean Levins, supplied the minor with alcohol on multiple incidents, and provided prescription drugs from your own personal prescription containers of Trazodone, outside of the practice of pharmacy or dispensing.

The technician also alleges from September, 2022, to August, 2023, that you continued with repeated attempts to communicate with him by phone, texts, and social media, causing him to block you from phone or instant messaging, which then lead to your attempt to visit him while he was at work, and to make contact with the technicians mother and/or sister, which was considered by the technician as harassment.

Please respond to the above allegations and provide your explanation of the incidents.

PLEASE INCLUDE DETAILS OF ANY CORRECTIVE ACTION TAKEN OR PLANNED ON YOUR PART RELATING TO YOUR:

☐ Practice of Pharmacy ☐ Responsibilities as Pharmacist-in-Charge (PIC) ☐ Responsibilities as permitholder of the pharmacy

Your written response will be included as part of the investigation report submitted to the Board. Your written response or documentation should be provided to the Inspector at the address/email/fax indicated below before the deadline provided. ***If your response arrives after the deadline, the investigation report will be submitted to the Board without a response from you.*** Please note 20 CSR 2220-2.010(7) states, in part: "Except as otherwise authorized by law, a licensee, permittee, or registrant of the board must cooperate with any investigation or inspection conducted by or on the board's behalf. Cooperation includes responding fully and promptly to questions,..."

RESPONSE DEADLINE	
1/5/2024	
EMAIL OR FAX RESPONSE TO BELOW	
INSPECTOR	
Scott Spencer	
EMAIL ADDRESS	**FAX NUMBER**
scott.spencer@pr.mo.gov	(573) 526-3464

MO 375-0759 (9-2022)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
09/29/2023	12/28/2023	MO	Warrenton	Warren

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2023-003652	MO BOP

Reason/Charge
Dismissed from employment- gross misconduct

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Sean Levins	N/A

Name of Business/Industry/Entity
Walmart

Provide explanation below:

I was discharged from Walmart Pharmacy for gross misconduct. The MO Board of Pharmacy reached out asking to meet with me in regards to my dismissal. I met with a board inspector, Scott Spencer, on December 14, 2023.

In regards to my misconduct, the BOP questioned me about a technician "LL", who also is my cousin and godson. Between July 2022 and Sept 2022, LL was allowed to drink alcohol at my residence approximately 2-3 times. Sometimes alcohol was provided by LL, and at times it was from my own personal supply. This was done with the stipulations that LL must remain at my residence while under the influence as a safety precaution. He was not allowed to leave or drive if he was under the influence of alcohol.

At one point, LL mentioned he had difficulty sleeping, and I provided a single trazodone tablet to LL from my own personal prescription. I deeply regret having been a "safe house" for him and for providing him a trazodone tablet.

Additionally, LL made complaints of harassment toward him between September 16, 2022 and August 3, 2023. LL stated that I continued to call, text, and use social media to keep in contact, at which time he blocked me. And then alleged that I visited him at work and remained in contact with his mother and sister. I did not know that LL was wanting to discontinue contact with me, and as a 19 year old college student, I just thought it was laziness on his part. There was several times that I stopped in the store that LL worked at. My mother-in-law lives less than 1 mile from the store, I would visit my old technicians and coworkers (as I was a staff pharmacist from Oct 2017 to Nov 2020 at that location) or to visit my optometrist who was based out of that store for my yearly eye check ups, contacts, and glasses adjustments.

There were times that LL was there that I would say hi, we could chat for a few minutes, or I would chat with his coworkers that were old technicians of mine. There were also times he was not present, but I still had stopped by the pharmacy. I had become deeply worried about his lack of contact with me knowing his previous mental health issues, and his abrupt stopping of response. I would reach out to LL, hoping to get a response, to discuss what was going on in his life, or if I had upset him in some way. In late October 2022, I was at the store, and he did not have a coat but was doing curbside deliveries. I offered him the extra coat I keep in my car, since it had become colder throughout the day. He accepted and came to my car to get it. While I felt like he was just overwhelmed by school at that point since he was still talking to me in person, his texting behavior seemed to make sense. I would speak to his household family (including mother and sister), who stated he has had phases like this before, and to give him time and he would come around, just keep reminding him I am here. Knowing how it feels to be in a stressed or depressed mood, I continued to reach out every so often, hoping to spur a conversation. If at any point I had been asked by LL, I would have been happy to cease communication with him. I truly thought I was reminding him I was there for him. I am sorry for continuing to reach out at this point.

Original Signature (electronic, copies or stamps not accepted)

3/18/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

SEAN LEVINS

Print Name

Original Signature, no copies or stamps accepted

1/17/2024

Date

Board Use Only	Date Received:	Amount: 250.00 V#1111
	NAPLEX:	MPJE:

16

16A

[redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information

First: Braden Middle: Placek Last: Uppinghouse

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: DVM Practitioner License #: 2997-A Specialty: None

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Tropicana Animal Hospital

Practice Address: 2385 East Tropicana Ave Suite #: N/A

City: Las Vegas State: NV Zip:

Telephone: 702 736 4944 Fax: 702 736 5080 Email: [redacted]

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

✓ NPDBx

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
7/8/2019 11/9/2016	2/18/2020 8/9/2016	Mo Mo	Columbia Columbia	Boone Boone

Case # 19BA-CR02988
16-208

Governing, licensing, Arresting Presiding Body/Agency/Court 13th Judicial Circuit Court, Boone County Missouri
Columbia Municipal Court

Reason/Charge DWI - Prior
BAC - Excessive Blood Alcohol Content

Plaintiff/Defendant/Claimant/Respondent State of Missouri / Braden Upping House
Columbia Municipal court / Braden Upping house

Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

[redacted]
Original Signature (electronic, copies or stamps not accepted)

4/25/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brad Uppinghouse — 4/25/24

Print Name (First, Last) — Date

[redacted] — 4/25/24

Original Signature (electronic, copies or stamps not accepted) — Date

Board Use Only: Date Processed: _____ Amount: $200 (Check 182)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR VETERINARIAN AUTHORITY TO DISPENSE DRUGS

Non-Refundable $150 fee

Rev (06/09/2021)

What types of drug(s) will you be dispensing?

☒ Dangerous Drugs AND Controlled Substances

☐ Dangerous Drugs ONLY

Section 1: Personal Information

First: Braden Middle: Placek Last: Uppinghouse

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: DVM Practitioner License #: 2997

(You MUST have a current and active license with your respective BOARD to apply for and maintain a dispensing registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Tropicana Animal Hospital

Practice Address: 2385 E Tropicana Ave Suite #:

City: Las Vegas State: NV Zip: 89119

Telephone: 702 736 4944 Fax: Email: [redacted]

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable?		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable?		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 4: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:
BAC	Mo	1/9/2016	16-208	Boone	Columbia Municipal
~~DWI~~ DWI	Mo	7/8/2019	19BA-CR02982	Boone	13th Judicial Circuit Court

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brad Uppinghouse
Print Name (First, Last)

[redacted]
Original Signature (electronic, copies or stamps not accepted)

4/4/2024
Date

Board Use Only Received: 4/8/24 Amount: $150-Check 187

I am a recovering alcoholic. Reflecting back on my upbringing gave me insight into why I used alcohol as a coping mechanism. I grew up in a home and community where daily drinking was normal. As a child, I did not recognize the signs of alcohol abuse but, instead, associated the signs of intoxication I saw in my parents just as exhaustion from working all day. My family's alcohol abuse was first brought to my attention by my friends in middle school and early high school. While my parents appeared to drink often, there was never a moment in which I felt they were not able to fulfill their responsibilities and had the means to raise me well. From my perspective, their alcohol abuse did not appear to be problematic.

When I went off to college, the overconsumption of alcohol remained prevalent. Even in a new environment with new friends, it was always present. In college, alcohol was commonly used to bring friends together and was, of course, often used to relieve the stress of classes. Reflecting back on this time, I am now able to recognize the stress I placed on myself to do well in class and maintain a high grade point average. I relied on alcohol to relieve my stress in the same way I have seen my family and friends do my entire life.

I graduated from Mizzou with a bachelor's degree in biological sciences and began working at a reproductive services lab for the University of Missouri. The new challenge for me became developing skills in a brand new career. For anyone, this can be a daunting experience on its own. At this time, I had also became completely financially independent. This was the first time I felt a significant amount of financial pressure because I needed to manage my limited income as best as I possibly could. I wanted a good future for myself and that meant I needed to excel in my current job as well properly plan financially on my own. These novel stresses coupled with the fact I had lived alone at the time lead to a deep depression. Just like college, I placed a lot of pressure on myself which often led to drinking to alleviate the pain, just as I, my parents, and what I thought my friends had done before. I was eventually able to seek help for my depression. I was prescribed antidepressants and was managed medically, however, I never saw a therapist, so my problem with alcohol had not been identified at that time.

After years of working at the lab, I had several co-workers that I trained who eventually left to start vet school. I was really good friends with all of my co-workers at the lab, but seeing them head off to start new chapters in their lives, whether it was vet school or other careers, allowed me to develop new aspirations for myself as well. I gave serious consideration to applying to vet school and started completing prerequisites while shadowing veterinarians. It was a long road trying to complete classes and gain general practice experience while maintaining a full time job. During this was the first time that I had to face the consequences of my addiction and was convicted of having excessive blood alcohol content or BAC. I was nervous that I ruined my future career. I convinced myself that it was a mistake I wouldn't repeat. I thought I could make good choices related to my consumption of alcohol.

On my third vet school application, I was finally placed on the waitlist and didn't hear from Mizzou until three weeks before school started that a spot had opened up. I knew that starting this new part of my life was going to be incredibly challenging. Mizzou is, of course, a vet school with an accelerated program (2&2) requiring me to learn how to study and manage my time

effectively as possible. The pace of school was difficult to maintain and led to even more anxiety than I had ever experienced before. Restful sleep became difficult to acquire for weeks on end. This was due to the anxiety of school which, in turn, made studying difficult because I was constantly in a default of adequate rest. This was a vicious cycle of being too tired to study from lack of sleep, making me fall behind on my school work, increasing my anxiety substantially and therefore making it difficult to sleep -- repeating over and over again.

Until halfway through vet school, I never developed healthy mechanisms for dealing with stress, anxiety, or depression. I also had the mentality from my upbringing that a man should be stoic about their emotions and talking about it was not even a consideration. I never thought that I had large enough problems that would benefit from professional help anyways. Every person in my class was going through the same stresses that I was, so in my opinion, I never thought it was worth seeking help for. I used the method which I had seen with my friends and family and which I have relied on most of my life: alcohol abuse. I am extremely lucky and grateful that no one was harmed because of my addiction. I felt like my addiction was entirely innocent because I kept my drinking confined to my home or when I was having dinner with friends and family. I was under the assumption that I was not hurting anyone by drinking as I did, I will never forget, because my inability to recognize my abuse as a problem led to one of the biggest mistakes of my life, something I can no longer take back and was convicted of driving under the influence or DUI. This was a pivotal point in my life. After that day, I realized that I am putting so many others at risk for my addiction. It isn't just myself that is trying to overcome my substance abuse.

Now that I have graduated from vet school, I realize I have the support system I always needed. I used alcohol to help manage the problems of my life and I am fortunate enough to have family and friends that are willing to help me with my addiction. I am learning new ways to manage my stress and anxiety through self-reflection and working on talking about my feelings with others to allow them to help me through difficult situations. Therapy will be a consistent source of help for me as well as the support from my family. As of now, I am abstaining from alcohol use. It is incredibly difficult to put into words the amount of regret I have for not seeking help sooner and identifying my problem with alcohol abuse. However, it is important for me to continue to look forward, not backwards. There are times when I am required to reflect on my past in order to identify where my problems lie. I can see the amount of change I've made already and I am happy with this progress. I look forward to being able to growing as a person and a doctor in my new chapter of life, with a new mindset and a brighter outlook on the life I want to have for myself.



Case Summary

UPPINGHOUSE, BRADEN PLACEK - BAC - Excessive Blood Alcohol Content/ ORD577.0-021Y20215404-0
Court: 6M-16-00123-MT
Law: 130797552
Agency: Columbia Municipal Court
CaseID: 16-208
Type: Traffic - Municipal
Received Date: 1/19/2016
Status: Disposed
Status Date: 8/9/2016
[redacted]

Involvements
Primary Involvements
UPPINGHOUSE, BRADEN PLACEK Defendant
City Prosecutor
Rinck, Robert - 56952 Prosecuting Attorney
Columbia Municipal Court (6M-16-00123-MT)
Morgan, Jack H - AMJ-2 Judge
Columbia Police Department (130797552)
Lenger, Scott - 2098 Police Officer
Defense Attorney
Popplewell, Andrew - 57183 Defense Attorney

Charges
1. 14-613 - BAC - Excessive Blood Alcohol Content/ ORD577.0-021Y20215404-0 Occurred: 1/9/2016
$0-500 and/or 0-3 months jail TRAF Y
Count History: 14-612 -Driving while intoxicated/ ORD577.0-041Y20215404.0 Change Date: 8/9/2016
Change Type: Statute
Attribute
Alcohol Related Offense
UPPINGHOUSE, BRADEN PLACEK Defendant
Plea: Guilty Plea Plea Date: 8/9/2016 Disposition: Guilty Plea Dispo Date: 8/9/2016
Sentence: 8/9/2016 Fine Assessed
Condition: Satop ordered in comp w/MO law

Events (8)
1/19/2016 1:51:00 PM | Conversation | Completed
Notes: DWI
2/18/2016 1:30:00 PM | Arraignment | Entry of Appearance Filed
Rinck, Robert - 56952 (Prosecuting Attorney)
Morgan, Jack H - AMJ-2 (Judge)
Lenger, Scott - 2098 (Police Officer)
UPPINGHOUSE, BRADEN PLACEK (Defendant)
3/8/2016 9:00:00 AM | Disposition Hearing | Continued at Attorney's Request
Rinck, Robert - 56952 (Prosecuting Attorney)
Popplewell, Andrew - 57183 (Defense Attorney)
Morgan, Jack H - AMJ-2 (Judge)
UPPINGHOUSE, BRADEN PLACEK (Defendant)
4/12/2016 9:00:00 AM | Disposition Hearing | Continued at Attorney's Request
Rinck, Robert - 56952 (Prosecuting Attorney)
Popplewell, Andrew - 57183 (Defense Attorney)

TRUSTWAVE

Case Summary

Morgan, Jack H - AMJ-2 (Judge)
UPPINGHOUSE, BRADEN PLACEK (Defendant)

5/10/2016 9:00:00 AM | Disposition Hearing | Continued at Attorney's Request
Rinck, Robert - 56952 (Prosecuting Attorney)
Popplewell, Andrew - 57183 (Defense Attorney)
Morgan, Jack H - AMJ-2 (Judge)
UPPINGHOUSE, BRADEN PLACEK (Defendant)

6/14/2016 9:00:00 AM | Disposition Hearing | Continued at Attorney's Request
Rinck, Robert - 56952 (Prosecuting Attorney)
Popplewell, Andrew - 57183 (Defense Attorney)
Morgan, Jack H - AMJ-2 (Judge)
UPPINGHOUSE, BRADEN PLACEK (Defendant)

7/12/2016 9:00:00 AM | Disposition Hearing | Continued at Attorney's Request
Rinck, Robert - 56952 (Prosecuting Attorney)
Popplewell, Andrew - 57183 (Defense Attorney)
Morgan, Jack H - AMJ-2 (Judge)
UPPINGHOUSE, BRADEN PLACEK (Defendant)

8/9/2016 9:00:00 AM | Disposition Hearing | Disposed
Rinck, Robert - 56952 (Prosecuting Attorney)
Popplewell, Andrew - 57183 (Defense Attorney)
Morgan, Jack H - AMJ-2 (Judge)
UPPINGHOUSE, BRADEN PLACEK (Defendant)

Case Status History (8)

Filing Cabinet (8)

Case Obligations

Columbia Municipal Court

Personal Obligation

Obligation	Pay By	Due Date	Obligation Amount	Amount Paid	Amt Left To Pay
Court Costs/Clerk Fee	1--UPPINGHOUSE, BRADEN-14-613	8/10/2016	$12.00	$12.00	$0.00
Crime Victim's Compensation/City	1--UPPINGHOUSE, BRADEN-14-613	8/10/2016	$0.37	$0.37	$0.00
Crime Victim's Compensation/State	1--UPPINGHOUSE, BRADEN-14-613	8/10/2016	$7.13	$7.13	$0.00
Law Enforcement Training/State Police Training	1--UPPINGHOUSE, BRADEN-14-613	8/10/2016	$1.00	$1.00	$0.00
Inmate Security Prisoner Fee	1--UPPINGHOUSE, BRADEN-14-613	8/10/2016	$2.00	$2.00	$0.00

Case Summary

DWI Recoupment Fee	1--UPPINGHOUSE, BRADEN-14-613	8/10/2016	$125.00	$125.00	$0.00
Fine	1--UPPINGHOUSE, BRADEN-14-613	8/10/2016	$500.00	$500.00	$0.00
	Total Personal Obligation(s):		$649.50	$649.50	$0.00
	Total Case Obligation(s):		**$649.50**	**$649.50**	**$0.00**

IN THE 13TH JUDICIAL CIRCUIT COURT, BOONE COUNTY MISSOURI

Judge or Division : STEPHANIE MARIE MORRELL (52231) DIV11	**Case Number : 19BA-CR02988** ☐ Change of Venue from Offense Cycle No : PZ000084
State Of Missouri vs. Defendant: BRADEN PALCEK UPPINGHOUSE [redacted] [redacted] SEX : M	Assistant Prosecuting Attorney/MO Bar No: NICHOLAS JOHN KOMOROSKI (52675) Defense Attorney/MO Bar No : BRENT ERIC HADEN (54148)
	Appeal Bond Set Date : Amount :

Judgment

	Charge #	Charge Date	Charge Code	Charge Description
Original Charge:	1	08-Jul-2019	577.010-030Y201754.0	Dwi - Prior (**Misdemeanor A RSMo: 577.010**)

Disposition: 18-Feb-2020 Guilty Plea
Order Date: 18-Feb-2020 **Sentence or SIS :** Incarceration Jail
Length : 90 Days **Start Date :** 18-Feb-2020
Text : Count 1 - Defendant sentenced to 90 Days Jail, SES, 2 Years Probation and Court Cost The State appears by Assistant Prosecuting Attorney. The defendant appears in person with Haden. The defendant enters a plea of guilty. Pursuant to Rule 24.02, the Court determines that the plea is voluntarily made by the defendant, and the Court accepts the plea of guilty, and finds the Defendant guilty. The Court informs the Defendant of the terms of the finding of guilt as set out in the judgment and sentence. See Judgment sheet. SMM/XI (mc)

EXECUTION OF SENTENCE SUSPENDED

Program : PROBATION
Classification : UNSUPERVISED
Associated To : Charge 1
Start Date : 18-Feb-2020
End Date : 18-Feb-2022
Agency : Boone County Courthouse
Outcome : Successfully Completed
Due to End : 18-Feb-2022

Defendant's Probation has not been revoked.

The Court orders:

That Judgment entered in favor of the State of Missouri and against the defendant for the sum of **$10.00** for the Crime Victims Compensation fund. Judgment is **Satisfied.**

Costs taxed against **Defendant**

The Court further orders:

18-Feb-2020 Judgment CVC $10 - Alcohol

18-Feb-2020 Defendant Sentenced

Count 1 - Defendant sentenced to 90 Days Jail, SES, 2 Years Probation and Court Cost
The State appears by Assistant Prosecuting Attorney. The defendant appears in person with Haden. The defendant enters a plea of guilty. Pursuant to Rule 24.02, the Court determines that the plea is voluntarily made by the defendant, and the Court accepts the plea of guilty, and finds the Defendant guilty. The Court informs the Defendant of the terms of the finding of guilt as set out in the judgment and sentence. See Judgment sheet.
SMM/X! (mc)

So Ordered on: 19BA-CR02988 ST V BRADEN PLACEK UPPINGHOUSE (CB) (COUP)

_____ _____

Date Judge

I certify that the above is a true copy of the original Judgment and Sentence of the court in the above cause, as it appears on record in my office.

(Seal of Circuit Court)

Issued on:

_____ _____

Date Clerk

Braden Uppinghouse

Legal First Name: Braden

Legal Last Name: Uppinghouse

Previous or Other Name(s):

Licenses

License Number	License Category	License Status	Initial Licensure Date	License Expiry Date
2997-A	Veterinarian	Active	Jun-11-2021	Jun-30-2025

Notices, Restrictions and Findings

Type	Effective Date	Summary	Completion Date	Attachments
None.				

Places of Work

Name	Street Address	City	Postal Code	Start Date	End Date
Tropicana Animal Hospital	2385 East Tropicana Avenue	Las Vegas	89119	May-24-2021	N/A

17

17A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

[redacted]

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information

First: KRISTIN Middle: Adele Last: Hestdalen

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephon[redacted] Email: [redacted]

Degree: MD Practitioner License #: 10215 Specialty: Adult, Child + Adolescent Psych

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Lakes Crossing Center

Practice Address: 500 Galletti Way Suite #:

City: Sparks State: NV Zip: 89431

Telephone: 775-688-1900 Fax: (775) 687-7570 Email:

↳ Division of Public + Behavioral Health

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	X	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
8/29/2022		WA	WALLA WALLA	WALLA WALLA
Case # —	Governing, licensing, Arresting Presiding Body/Agency/Court NA			
Reason/Charge I entered sober living facility called Hope Street after I relapsed				
Plaintiff/Defendant/Claimant/Respondent * I was there from 8/29/22 - 3/31/24 (19 months)	Lawsuit/Arbitration/Bankruptcy			
Name of Business/Industry/Entity Hope Street Homes				

Provide explanation below:

NSBOP CS Registration – Explanatory Answers

Explanatory Answer for Question #1

I am in recovery for an alcohol addiction and have been at Hope Street, a women's sober living home since August 2022; my date of sobriety is August 28, 2022. I have been actively participating in treatment through Southworth Associates, overseen by Dr. Mark Broadhead, since January 2023 including random monitoring tests, attendance at 12-step meetings and meetings with my sponsor in addition to meeting with my therapist and being followed by my treating psychiatrist. Southworth provides monthly reports to the Nevada State Board of Medical Examiners regarding my compliance with the program. I will be continuing with monitoring and treatment when I permanently return to the Reno area in July 2024.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

6/27/2024

Date

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	X	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question #2. **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
11/20/2019	8/30/2021	NV	Reno	Washoe County
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
20CR-15561	Reno Municipal Court			
Reason/Charge				
DUI				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
Kristin Westdalen				
Name of Business/industry/Entity				

Provide explanation below:

<u>Explanatory Answer for Question #2</u>

On November 7, 2019, I pleaded guilty to and was convicted of misdemeanor careless driving in Reno Justice Court which resolved two misdemeanor charges from November 21, 2018; DUI and Failure to Decrease Speed or Use Due Care. I was sentenced to thirty days jail time which was suspended. I paid $600 in fines and fees, attended a victim impact panel and completed eight hours of alcohol abuse education. All requirements of the Court were completed.

On August 30, 2021, a misdemeanor conviction of Careless Driving was imposed against me in Reno Municipal Court, case no. 20CR-15561. This was the conclusion of a DUI misdemeanor charge filed against me in November 2020. I pleaded guilty to the reduced charge of Careless Driving on August 30, 2021 and was sentence to a term of 120 days in jail; the sentence was suspended for a period of two years on the condition that I complete a DUI level 3 school, however I was allowed to use proof of my on-going counseling to comply with this requirement; I was required to complete a Victim Impact Panel; was required to submit to random testing, however I was again allowed to submit results of my on-going program monitoring at the time to satisfy this requirement. Finally, I was assessed fines and fees totaling $403.00. The case was fully closed on August 30, 2023.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

06/27/2024

Date

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	X	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question #2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
11/21/2018	11/7/2019	NV	Reno	Washoe
Case # Will get ASAP ↓ #RCR2018-099531		Governing, licensing, Arresting Presiding Body/Agency/Court Reno Justice Court		
Reason/Charge DUI				
Plaintiff/Defendant/Claimant/Respondent myself		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

Explanatory Answer for Question #2

On November 7, 2019, I pleaded guilty to and was convicted of misdemeanor careless driving in Reno Justice Court which resolved two misdemeanor charges from November 21, 2018; DUI and Failure to Decrease Speed or Use Due Care. I was sentenced to thirty days jail time which was suspended. I paid $600 in fines and fees, attended a victim impact panel and completed eight hours of alcohol abuse education. All requirements of the Court were completed.

On August 30, 2021, a misdemeanor conviction of Careless Driving was imposed against me in Reno Municipal Court, case no. 20CR-15561. This was the conclusion of a DUI misdemeanor charge filed against me in November 2020. I pleaded guilty to the reduced charge of Careless Driving on August 30, 2021 and was sentence to a term of 120 days in jail; the sentence was suspended for a period of two years on the condition that I complete a DUI level 3 school, however I was allowed to use proof of my on-going counseling to comply with this requirement; I was required to complete a Victim Impact Panel; was required to submit to random testing, however I was again allowed to submit results of my on-going program monitoring at the time to satisfy this requirement. Finally, I was assessed fines and fees totaling $403.00. The case was fully closed on August 30, 2023.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

6/27/24

Date

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	X	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

In Question #3. Provide all the following ***where applicable***:

Date of Event/Arrest	Disposition Date	State	City	County
12/13/2019	6/8/2020	NV	Reno	USA

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
19-228-CS-N	NV State Board of Pharmacy

Reason/Charge: Writing controlled substance prescriptions on an expired license

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Self	

Name of Business/Industry/Entity:

Provide explanation below:

Explanatory Answer for Question #3

The Nevada State Board of Pharmacy ("NVBOP") issued me a public reprimand pursuant to a Stipulation and Order which was effective on June 10, 2020. In October 2018, I inadvertently allowed my Nevada controlled substance registration to expire; however, I continued to write controlled substance prescriptions until realizing the error. The NVBOP filed a disciplinary Accusation against me on December 13, 2019, arising from the prescriptions I had written on the expired controlled substance registration. I entered into the Stipulation referred to above which resolved the matter.

The Nevada State Board of Medical Examiners ("NSBME") subsequently filed a disciplinary Complaint on February 12, 2021, based upon on the action taken by the NVBOP. I entered into a settlement with the NSBME on March 5, 2021, to resolve the matter; pursuant to that settlement agreement, the NSBME also issued a public reprimand.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

6/27/2024

Date

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	X	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to the above #4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/13/2019	6/8/2020	NV	Reno	USA

Case #: 19-228-CS-N

Governing, licensing, Arresting Presiding Body/Agency/Court: NV State Board of Pharmacy

Reason/Charge: Writing controlled substances on an expired license.

Plaintiff/Defendant/Claimant/Respondent: myself

Lawsuit/Arbitration/Bankruptcy:

Name of Business/Industry/Entity:

Provide explanation below:

Explanatory Answer for Question #4
As described in the explanation to Question #3, the NSBOP took disciplinary action against me related to my continuing to write controlled substance prescriptions after the lapse of my Nevada controlled substance registration.

*See also explanation for #3 which includes explanation reprimanding me for NSBME's

[redacted]
Original Signature (electronic, copies or stamps not accepted)

6/27/2024
Date

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	X	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # #5 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/12/2021	03/08/2021	N	Reno	USA

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
21-25351-1	NSBME

Reason/Charge: For violation of statutes and regulations of the NV State Board of Pharmacy

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
myself	

Name of Business/Industry/Entity:

Provide explanation below:

See explanation for #3 as well as the copy of the settlement agreement with the NSBME.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

06/27/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kristin Hestdalen
Print Name (First, Last)

6/27/2024
Date

[redacted]
Original Signature (electronic, copies or stamps not accepted)

6/27/2024
Date

Board Use Only: Date Processed: 7/2/24 Amount: $200.00

STEVE SISOLAK
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

March 23, 2022

VIA CERTIFIED U.S. MAIL

Kristin Hestdalen, MD
[redacted]

Re: NOTICE OF INACTIVE STATUS – Registration No. CS11061 (Case No. 22-076-CS-N)

Dear Dr. Hestdalen:

The Nevada State Board of Pharmacy (Board) has been notified that your License No. 10215 from the Nevada State Board of Medical Examiners has been placed on inactive status pursuant to NRS 630.255.

Please be advised that pursuant to Nevada Administrative Code Chapter 453 as amended by LCB File No. R071-19, your Certificate of Registration No. CS11061 with the Board is placed on inactive status effective immediately. You may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance. Your access to the Nevada Prescription Monitoring Program (PMP) database is suspended effective immediately. You may petition at any time for reinstatement of your registration and your PMP access.

You may request a hearing before the Board to contest the placement of your Certificate of Registration No. CS11061 on inactive status by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Please be aware that the foregoing does not preclude a formal investigation or filing of an accusation pursuant to NRS 639.241. If you have any questions, please do not hesitate to contact me at 775-850-1440.

Sincerely,

J. David Wuest, R.Ph.
Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **KRISTIN ADELE HESTDALEN, M.D.,** **Respondent.**	**Case No. 21-25351-1**

FILED
MAR - 8 2021
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Aaron Bart Fricke, Esq., Senior Deputy General Counsel for the Board and attorney for the IC, and Kristin Adele Hestdalen, M.D. (Respondent), a licensed physician in Nevada, assisted by her attorney, Lyn E. Beggs, Esq., of the law firm of Law Offices of Lyn E. Beggs, PLLC, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act). Her license was originally issued on July 1, 2002 (License No. 10215).

2. On February 12, 2021, in Case No. 21-25351-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges one (1) violation of NRS 630.306(1)(b)(3), Violation of Statutes and Regulations of the Nevada State Board of Pharmacy.

3. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

[1] All agreements and admissions made by Respondent are solely for final disposition of these matters and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

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4. Respondent was properly served with a copy of the Complaint, has reviewed and understands the Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of the Complaint.

5. Respondent is hereby advised of her rights regarding these administrative matters, and of her opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in these administrative matters as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at her own expense, in the preparation and presentation of her defense, the right to confront and cross-examine the witnesses and evidence against her, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to her.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon her and the Board.

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///

///

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges she is represented by counsel, and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that she knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with these administrative matters. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to her or that may apply to her in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges

that Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts that if these matters were to proceed to hearing, she has evidence, witnesses, expert witness(es) and defenses to the count/claim alleged in the Complaint, but for the purposes of resolving these matters and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve the Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count I of the Complaint, NRS 630.306(1)(b)(3), Violation of Statutes and Regulations of the Nevada State Board of Pharmacy.

b. Respondent shall pay a fine of five hundred dollars ($500.00) within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement.

c. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement, in the amount of six hundred fifty-three dollars and sixty-nine cents ($653.69).

d. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

e. Respondent shall receive a Public Letter of Reprimand.

f. All other claims and allegations arising from the specific claim alleged in the Complaint shall be dismissed with prejudice.

6. **Release From Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to

OFFICE OF THE GENERAL COUNSEL
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information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement** The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of the Complaint at an upcoming Board meeting at the Board's earliest convenience, and Respondent hereby waives notice of the same, whether under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, or otherwise. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex parte, without notice or opportunity to be heard on her part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to these matters. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and any and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

///

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
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(775) 688-2559

9. Effect of Rejection of Agreement by Board. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering the Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that she shall not seek to disqualify any such member absent evidence of bad faith.

10. Binding Effect. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. Forum Selection Clause. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the parties consent to such jurisdiction and agree that jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. Attorneys' Fees and Costs. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. Failure to Comply With Terms. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order To Show Cause Hearing on revocation, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to any civil and administrative collection efforts available.

DATED this 27th day of February, 2021.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: [redacted]
Aaron Bart Fricke, Esq., Senior Deputy General Counsel
Attorney for the Investigative Committee

DATED this 26th day of February, 2021.

LAW OFFICES OF LYN E. BEGGS, PLLC

By: [redacted]
Lyn E. Beggs Esq., Attorney for Respondent

DATED this 25th day of February 2021.

[redacted]
Kristin Adele Hestdalen, M.D., Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER

IT IS HEREBY ORDERED, that the foregoing Settlement Agreement (Case No. 21-25351-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 5th day of March, 2021, with the final total amount of costs due of six hundred fifty-three dollars and sixty-nine cents ($653.69)

DATED this 5th day of March, 2021.

[redacted]

Rachakonda D. Prabhu, M.D., President
Nevada State Board of Medical Examiners

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KRISTIN A. HESTDALEN, MD,** **Certificate of Registration No. CS11061,** **Respondent.**	**Case No. 19-228-CS-N** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Kristin A. Hestdalen, MD, Certificate of Registration No. CS11061, by and through counsel, Lyn E. Beggs, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.

2. On or about December 13, 2019, Board Staff properly served Respondent with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. Respondent is fully aware of her right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of her right to a hearing on the matters alleged in the Accusation, her right to reconsideration, her right to appeal and any and all other rights which may be accorded to her pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of Paragraphs 8, 13 and 14 below, Respondent hereby freely and voluntarily waives her rights to a hearing, reconsideration, appeal and any and all other rights related to this

action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*, that:

A. Respondent failed to timely renew her Certificate of Registration No. CS11061, which expired on October 31, 2018, in violation of NRS 639.210(13), and

B. While Respondent held an expired Nevada Controlled Substance Registration, she wrote two-hundred sixty-three prescriptions for controlled substances between November 1, 2018 and May 3, 2019, in violation of NRS 453.226(1), NRS 453.321(1)(a), NRS 639.100(1), NRS 639.2813(1) and/or 21 CFR § 1306.03.

7. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. The Board approved a new Controlled Substance Registration for Respondent on December 4, 2019, at which time Respondent appeared before the Board to answer questions and give testimony regarding her application and the facts and circumstances regarding this matter.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. Respondent Kristin A. Hestdalen, MD, Certificate of Registration No. CS11061, shall:

A. Receive a letter of reprimand from Board Staff regarding her duties and responsibilities as a prescribing practitioner;

B. Pay a fine of Five-Thousand Dollars ($5000.00) for the alleged violations; and

C. Pay Nine-Hundred and Fifty Dollars ($950.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on June 3, 2020. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or her counsel are not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board it shall be a public record pursuant to NRS 622.330.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Upon approval of this Stipulation by the Board, Respondent shall pay the fines agreed to herein by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, in monthly installments of $500.00 for ten months and due on the first date of each month commencing July 1, 2020.

15. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and costs agreed to herein by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order.

16. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of March, 2020

[redacted]

KRISTIN A. HESTDALEN, MD,
Certificate of Registration NoCS11061

Signed this 2nd day of March, 2020

[redacted]

BRETT RANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT this ___ day of March, 2020

[redacted]

LYN E. BEGGS, ESQ.
Counsel for Respondent

17B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

[redacted]

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☒ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information

First: Raymond Middle: Paul Last: Tangradi

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: MD 25891 Specialty: Psychiatry

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Southern Nevada Adult Mental Health Services (SNAMHS)

Practice Address: 1650 Community College Drive Suite #: —

City: Las Vegas State: NV Zip: 89146

Telephone: (702) 486-4400 Fax: — Email: —

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

NPDBV

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

(See enclosed Explanatory Answers in additional papers)

* Also supporting documentation attached

[redacted]

Original Signature (electronic, copies or stamps not accepted)

6/16/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Raymond Tangredi MD
Print Name (First, Last)

6/16/2024
Date

[redacted]
Original Signature (electronic, copies or stamps not accepted)

6/16/2024
Date

Board Use Only: Date Processed: 6/20/24 Amount: $200.00

Explanatory Answer for Section 5, Question #1

I was officially diagnosed with Bipolar Disorder type I in the winter of 2016 after multiple years of suffering from mental health issues which had a significant impact on the circumstances which resulted in the board administrative actions discussed in the answer to Quest #3 below. I am currently prescribed Depakote by my treating provider which has ameliorated my symptoms significantly. Additionally, I discovered that my my bipolar symptoms were significantly impacted by a strong seasonal affective component. I lived and worked in the Pacific Northwest during the height of my symptoms. After relocating to Las Vegas several years ago, I found that my bipolar symptoms in conjunction with continuing my prescribed medication, have been substantially reduced. I continue seeing my treating provider on a regular basis and my diagnosis does not currently impact my ability to practice medicine safely.

Explanatory Answer for Section 5, Question #2

I was arrested on December 5, 1999, in Clackamas County, Oregon, for misdemeanor Assault IV and Menacing for an alleged domestic dispute with my wife at the time arising out of a verbal argument that briefly became a physical altercation. The charges were rejected by the District Attorney's office and no formal charges were filed.

Explanatory Answer for Section 5, Question #3

In June 2015, the Oregon Medical Board (OMB) requested that I entered into an Interim Stipulated Order agreeing not to practice until the conclusion of an administrative investigation; that order was effective July 2, 2015.

On July 15, 2016, the Washington Medical Board (WMB) issued an Order of Suspension of my medical license which had previously expired. The Order of Suspension was based solely on an Interim Stipulated Order in Oregon.

In February 2016, the OMB filed a Complaint and Notice of Disciplinary Action. The complaint alleged sexual misconduct with a patient and boundary issues. In August 2016 I signed a stipulation to retire my medical license under investigation, which was accepted by the OMB in October 2016; no findings or admissions related to the allegations were made in the stipulation. I also agreed to surrender my expired medical license in Washington in October 2016 after retiring my license in Oregon.

John S. Foote, District Attorney for Clackamas County
Clackamas County Courthouse, 807 Main Street, Room 7, Oregon City, Oregon 97045
503 655-8431, FAX 503 650-8943, www.co.clackamas.or.us/da/

June 22, 2007

Nevada State Board of Medicine
1105 Terminal Way, # 301
Reno, Nevada 89502

RE: Ray Tangredi

To Whom It May Concern:

I have reviewed the computer record regarding an incident that occurred on or about December 5, 1999 involving allegations of domestic abuse involving Dr. Tangredi. This office received a piece of intake regarding that allegation on December 14, 1999. On December 21, 1999, Deputy District Attorney Dan Kelley rejected the case for the reason that the evidence was insufficient to charge Dr. Tangredi with a criminal offense. The statute of limitations on that action has now run, and the case cannot be filed.

If you have any further questions regarding this case, you may call me a [redacted]

Sincerely,

/s/

Christine L. Landers
Senior Deputy District Attorney

Bcc: Dr. Ray Tangredi
[redacted]

BEFORE THE

OREGON MEDICAL BOARD

STATE OF OREGON

In the Matter of RAYMOND PAUL TANGREDI, MD LICENSE NO. MD18328	)	INTERIM STIPULATED ORDER

1.

The Oregon Medical Board (Board) is the state agency responsible for licensing, regulating and disciplining certain healthcare providers, including physicians, in the state of Oregon. Raymond Paul Tangredi, MD (Licensee) is a licensed physician in the state of Oregon.

2.

The Board received credible information regarding Licensee that resulted in the Board initiating an investigation. The results of the Board's investigation to date have raised concerns to the extent that the Board believes it necessary that Licensee agree to cease the practice of medicine until the investigation is completed.

3.

In order to address the concerns of the Board, Licensee and the Board agree to enter into this Interim Stipulated Order, which is not an admission of any wrongdoing on the part of the Licensee, and provides that Licensee shall comply with the following conditions effective the date this Order is signed by Licensee:

3.1 Licensee voluntarily withdraws from the practice of medicine and his license is placed in Inactive status pending the completion of the Board's investigation into his ability to safely and competently practice medicine.

3.2 Licensee understands that violating any term of this Order will be grounds for disciplinary action under ORS 677.190(17).

///

3.3 Licensee must notify the Oregon Medical Board within 10 days as to how patients may access or obtain their medical records.

4.

At the conclusion of the Board's investigation, Licensee's status will be reviewed in an expeditious manner. Following that review, if the Board determines that Licensee shall not be permitted to return to the practice of medicine, Licensee may request a hearing to contest that decision.

5.

This Order is issued by the Board pursuant to ORS 677.265(1) and (2) for the purpose of protecting the public, and making a complete investigation in order to fully inform itself with respect to the performance or conduct of the Licensee and Licensee's ability to safely and competently practice medicine. Pursuant to ORS 677.425, Board investigative materials are confidential and shall not be subject to public disclosure. However, as a stipulation this Order is a public document and is reportable to the national Data Bank and the Federation of State Medical Boards.

6.

This Order becomes effective the date it is signed by the Licensee.

IT IS SO STIPULATED THIS 2nd day of July, 2015.

SIGNATURE REDACTED

RAYMOND PAUL TANGREDI, MD

IT IS SO ORDERED THIS 2nd day of July, 2015.

State of Oregon
OREGON MEDICAL BOARD

SIGNATURE REDACTED

KATHLEEN HALEY, JD
EXECUTIVE DIRECTOR

BEFORE THE

OREGON MEDICAL BOARD

STATE OF OREGON

In the Matter of RAYMOND PAUL TANGREDI, MD LICENSE NO. MD18328	)))))	STIPULATED ORDER

1.

The Oregon Medical Board (Board) is the state agency responsible for licensing, regulating and disciplining certain health care providers, including physicians, in the state of Oregon. Raymond Paul Tangredi, MD (Licensee) is a licensed physician in the State of Oregon.

2.

On January 7, 2015, the Board opened an investigation after receiving credible information regarding Licensee's medical practice. The Board was concerned about serious professionalism and boundary issues and on July 2, 2015, Licensee entered into an Interim Stipulated Order with the Board in which he agreed to voluntarily cease the practice of medicine pending the completion of the Board's investigation. On February 24, 2016, the Board issued a Complaint and Notice of Proposed Disciplinary Action citing possible violations of the Medical Practice Act.

3.

Licensee and the Board desire to settle this matter by the entry of this Stipulated Order in which Licensee agrees to retire his license while under investigation, consistent with the terms of this Order. Licensee understands that he has the right to a contested case hearing under the Administrative Procedures Act (Oregon Revised Statutes chapter 183), and fully and finally waives the right to a contested case hearing and any appeal therefrom by the signing of this Order in the Board's records. Licensee neither admits nor denies, but the Board finds that Licensee engaged in conduct that violated ORS 677.190(1)(a) unprofessional or dishonorable

conduct, as defined in ORS 677.188(4)(a), and ORS 677.190(13) gross or repeated negligence. Licensee understands that this Order is a public record and is a disciplinary action that is reportable to the National Data Bank and the Federation of State Medical Boards.

4.

Licensee and the Board agree that the Board will close this investigation and resolve this matter by entry of this Stipulated Order, subject to the following conditions:

4.1 Licensee retires his license to practice medicine while under investigation, effective the date the Board Chair signs this Order.

4.2 The Interim Stipulated Order of July 2, 2015, is terminated the date this Order is signed by the Board Chair.

4.3 Licensee stipulates and agrees that any violation of the terms of this Order shall be grounds for further disciplinary action under ORS 677.190(18).

5.

This Order becomes effective the date it is signed by the Board Chair.

IT IS SO STIPULATED this 19th day of August 2016.

[redacted]

RAYMOND PAUL TANGREDI, MD

IT IS SO ORDERED this 6th day of October 2016.

OREGON MEDICAL BOARD

[redacted]

SHIRIN SUKUMAR, MD
Board Chair

STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of: RAYMOND P. TANGREDI, MD, License No. MD.MD.60248946, Respondent.	Master Case No. M2016-656 EX PARTE ORDER OF SUMMARY SUSPENSION

PRESIDING OFFICER: Jerry D. Mitchell, Health Law Judge.

This matter came before the Presiding Officer on delegation from and authorization by the Medical Quality Assurance Commission (Commission) on July 15, 2016, on an Ex Parte Motion for Order of Summary Action (Ex Parte Motion) brought by the Office of the Attorney General. The Commission issued a Statement of Charges alleging Respondent violated RCW 18.130.180(5). The Presiding Officer, after reviewing the Ex Parte Motion with its supporting declaration and exhibits, and the Statement of Charges, GRANTS the Ex Parte Motion. Respondent's license is SUSPENDED pending further disciplinary proceedings.

I. FINDINGS OF FACT

1.1 On October 21, 2011, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently expired in renewal. Respondent is not board certified but self designates his practice specialty as addiction psychiatry.

1.2 The Commission issued a Statement of Charges alleging Respondent violated RCW 18.130.180(5). The Statement of Charges was accompanied by all other documents required by WAC 246-11-250.

1.3 On July 2, 2015, the Oregon Medical Board entered an Interim Stipulated Order in a case regarding Respondent's license to practice medicine (Oregon Interim Order). The Oregon Interim Order provided that Respondent voluntarily withdraw from the practice of medicine pending the completion of the Board's investigation regarding Respondent's ability to safely and competently practice medicine.

1.4 On February 24, 2016, the Oregon Board issued Complaint and Notice of Proposed Disciplinary Action (Oregon Complaint) in the same case as the Stipulated Order. The Oregon Complaint alleges that Respondent violated the Oregon Medical Practice Act by engaging in sexual misconduct with one patient and committing repeated boundary violations with another.

1.5 On or about December 30, 2015, the Commission received a certified copy of Oregon Stipulated Order in Case. No. MD18328, that was entered by the Oregon Board on July 2, 2015. On or about April 8, 2016, the Commission received written notice from the Oregon Board that it issued the Oregon Complaint to Respondent on February 24, 2016, in the same case as the Oregon Interim Stipulated Order. The certified copy of the Oregon Interim Stipulated Order and the notice regarding issuance of the Oregon Complaint in the same case constitute conclusive proof of the violation of RCW 18.130.180(5).

1.6 The basis for the Oregon Stipulated Interim Order is substantially similar to RCW 18.130.180(1), (4), (7), (24), and WAC 246-919-630(2)(a) and (j).

II. CONCLUSIONS OF LAW

2.1 The Commission (and by delegated authority the Presiding Officer), has jurisdiction over Respondent's license to practice as a physician and surgeon. RCW 18.130.040.

2.2 The Commission has authority to take emergency adjudicative action to address an immediate danger to the public health, safety, or welfare. RCW 34.05.422(4); RCW 34.05.479; RCW 18.130.050(8); and WAC 246-11-300.

III. ORDER

3.1 Based on the Findings of Fact and the Conclusions of Law, it is ORDERED that Respondent's license to practice as a physician and surgeon is SUMMARILY SUSPENDED pending further disciplinary proceedings by the Commission. Respondent shall immediately deliver all licenses, (including wall, display, and/or wallet, if any), to the Commission.

3.2 It is HEREBY ORDERED that a protective order in this case is GRANTED. RCW 34.05.446(1) and WAC 246-11-400(2) and (5). This Protective Order prohibits the

release of health care information outside of these proceedings. Unless required by law, anyone involved in these proceedings must keep confidential and not disclose health care information obtained through these proceedings. Health care information includes information in any form "that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care." RCW 70.02.010(16). The parties may share the information with their attorney, if any.

Dated this 15 day of July, 2016

JERRY D. MITCHELL, Health Law Judge
Presiding Officer

For more information, visit our website at:
http://www.doh.wa.gov/PublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/Hearings.aspx

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Raymond P. Tangredi, MD
Master Case No.: M2016-656
Document: Agreed Order

Regarding your request for information about the above-named practitioner; attached is a true and correct copy of the document on file with the State of Washington, Department of Health, Adjudicative Clerk Office. These records are considered Certified by the Department of Health.

Certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld: **NONE**

If you have any questions or need additional information regarding the information that was withheld, please contact:

Customer Service Center
P.O. Box 47865
Olympia, WA 98504-7865
Phone: (360) 236-4700
Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Privacy Officer, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of **RAYMOND P. TANGREDI, MD** License No. MD60248946, Respondent.	**No. M2016-656** **STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER**

The Medical Quality Assurance Commission (Commission), through Lawrence J. Berg, Department of Health Staff Attorney, and Respondent, represented by counsel, Jennifer Smitrovich, stipulate and agree to the following.

1. PROCEDURAL STIPULATIONS

1.1 On or about July 18, 2016, the Commission issued a Statement of Charges and entered Ex Parte Order of Summary Suspension (Ex Parte Order) suspending Respondent's license pending further proceedings.

1.2 In the Statement of Charges, the Commission alleges that Respondent violated RCW 18.130.180(5).

1.3 The Commission is prepared to proceed to a hearing on the allegations in the Statement of Charges.

1.4 Respondent has the right to defend against the allegations in the Statement of Charges by presenting evidence at a hearing.

1.5 The Commission has authority to impose sanctions pursuant to RCW 18.130.160 if the factual allegations are proved at a hearing.

1.6 The parties agree to resolve this matter by means of this Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Agreed Order).

1.7 Respondent waives the opportunity for a hearing on the Statement of Charges if the Commission accepts this Agreed Order.

1.8 This Agreed Order is not binding unless it is accepted and signed by the Commission. This Agreed Order supersedes the Ex Parte Order.

1.9 If the Commission accepts this Agreed Order, it will be reported to the National Practitioner Data Bank (45 CFR Part 60), the Federation of State Medical Boards' Physician Data Center and elsewhere as required by law.

1.10 This Agreed Order is a public document. It will be placed on the Department of Health's website, disseminated via the Commission's electronic mailing list, and disseminated according to the Uniform Disciplinary Act (Chapter 18.130 RCW). It may be disclosed to the public upon request pursuant to the Public Records Act (Chapter 42.56 RCW). It will remain part of Respondent's file according to the state's records retention law and cannot be expunged.

1.11 If the Commission rejects this Agreed Order, Respondent waives any objection to the participation at hearing of any Commission members who heard the Agreed Order presentation.

2. FINDINGS OF FACT

Respondent and the Commission acknowledge that the evidence is sufficient to justify the following findings, and the Commission makes the following findings of fact.

2.1 On October 21, 2011, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently expired in renewal. Respondent is board certified in Psychiatry and Neurology, and he completed a fellowship at Oregon Health Science University in Addiction Psychiatry.

2.2 On July 2, 2015, the Oregon Medical Board (OMB) entered an Interim Stipulated Order in a case regarding Respondent's license to practice medicine (Interim Order). Respondent voluntarily withdrew from the practice of medicine pending the completion of the Board's investigation.

2.3 On February 24, 2016, the OMB issued Complaint and Notice of Proposed Disciplinary Action (Oregon Complaint) in the same case as the Interim Order.

2.4 On October 6, 2016, the OMB entered a Stipulated Order in which Respondent agreed to retire his Oregon license while under investigation.

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3. CONCLUSIONS OF LAW

The Commission and Respondent agree to the entry of the following Conclusions of Law.

3.1 The Commission has jurisdiction over Respondent and over the subject matter of this proceeding.

3.2 Respondent has committed unprofessional conduct in violation of RCW 18.130.180(5).

3.3 The above violations provide grounds for imposing sanctions under RCW 18.130.160.

4. AGREED ORDER

Based on the Findings of Fact and Conclusions of Law, Respondent agrees to entry of the following Agreed Order.

4.1 **Surrender.** Respondent agrees to SURRENDER his physician license, and agrees not to resume the practice of medicine in the state of Washington, including any temporary, emergency or volunteer practice. Respondent acknowledges that he is ineligible to renew, reactivate, or to practice subject to a retired active license as a physician in the state of Washington.

4.2 **Return of License:** Respondent agrees to immediately return his wallet license card and wall license certificate, if they exist, to:

Compliance Officer
Medical Quality Assurance Commission
Department of Health
P. O. Box 47866
Olympia, WA 98504-7866

4.3 **Effective Date.** The effective date of this Agreed Order is the date the Adjudicative Clerk Office places the signed Agreed Order into the U.S. mail.

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5. COMPLIANCE WITH SANCTION RULES

5.1 The Commission applies WAC 246-16-800, et seq., to determine appropriate sanctions. The sanction schedules stated in those rules do not address the alleged conduct in this case. RCW 18.130.390 and WAC 246-16-800(1)(d) require the Commission to use its judgment when the sanction schedules do not address the conduct in question.

5.2 WAC 246-16-800(2)(b)(iii) provides for surrender of a credential by a license holder as an alternative to sanctions consistent with the sanction rules.

5.3 Respondent retired his license to practice as a physician while under investigation in the state of Oregon where the underlying conduct occurred. The Commission has not conducted an independent investigation regarding the underlying allegations stated in the Oregon Complaint. Respondent is at the effective end of his practice and surrender alone is enough to protect the public.

6. RESPONDENT'S ACCEPTANCE

I, RAYMOND P. TANGREDI, MD, Respondent, have read and understand this Agreed Order. I agree to this Agreed Order solely for the purpose of resolving this proceeding. This Agreed Order may be presented to the Commission without my appearance. I understand that I will receive a signed copy if the Commission accepts this Agreed Order.

[redacted]

RAYMOND P. TANGREDI, MD
RESPONDENT

10/20/16
DATE

[redacted]

JENNIFER M. SMITROVICH, WSBA #37062
ATTORNEY FOR RESPONDENT

10/24/16
DATE

//

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7. COMMISSION'S ACCEPTANCE AND ORDER

The Commission accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED: Nov. 3, 2016.

STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

[redacted]
PANEL CHAIR

PRESENTED BY:

[redacted]
LAWRENCE J. BERG, WSBA#22334
DEPARTMENT OF HEALTH STAFF ATTORNEY

Raymond Paul TANGREDI

License Number:
25891

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Jun-13-2024

Expiration Date:
Jun-30-2025

Public Address:
PO Box 94674

Public City:
Las Vegas

Public State:
Nevada

Public ZIP Code:
89193

Public Country:
United States

Public Phone Number:
(702) 486-4400

Credential:
M.D.

Specialties

Specialty
Psychiatry
Addiction Psychiatry
Psychiatry
Urgent Care

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
University of Nevada, Las Vegas	Bachelor of Science	Aug-25-1983	Jul-07-1989
University of Nevada Reno School of Medicine	Medical Doctor Degree	Aug-29-1988	May-01-1992

Institution	Degree/Certificate	Date Enrolled	Date To
University of Nevada SOM / Reno , NV	Medical Doctor Degree	N/A	May-15-1992

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Providence Portland Medical Ctr / Portland , OR	Internship	Internal Medicine	Jun-23-1992	Jun-24-1993
Providence Portland Internal Medicine Residency Program	Internship	Internal Medicine	Jul-01-1992	Jul-01-1993
LAC + USC Psychiatry Residency	Residency	Psychiatry	Jul-01-2006	Jun-30-2007
LA County/Univ of Southern CA / Los Angeles , CA	Residency	Psychiatry	Jul-01-2006	Jun-30-2007
UNR School of Medicine	Residency	Psychiatry	Jul-01-2007	Jun-30-2009
University of Nevada SOM / Las Vegas , NV	Residency	Psychiatry	Jul-10-2007	Jun-30-2009
OHSU Addiction Psychiatry Fellowship	Fellowship	Addiction Psychiatry	Jul-01-2009	Jun-30-2010

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

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18

18A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (03/16/2023)

Section 1: General Information

First: Nicole Middle: Shriee Last: Brooks

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] 8th St

City: Las Vegas State: NV Zip: 89101

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258

Program/School Name: Northwest Career College

Address: 7398 Smoke Ranch Rd

City: Las Vegas State: NV Zip: 89128

Name of Program Director: Samantha Huntsman

Signature of Program Director:

Section 3: Employment Information

Pharmacy Name: License #:

Address:

City: State: Zip:

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	✓	
2. Are you a high school graduate or the equivalent?	✓	

High School Name: F.L. Schlagle Graduation Date OR Date GED obtained (mm/yy): 06/97

Address: 2214 N 59th St

City: Kansas City State: KS Zip: 66104

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 7: Personal and Professional History	Initials	
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: **WARNING** **You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.**	MB	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?	✓	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date 6/10/24

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Nicole Brooks

Print Name

Original Signature (electronic copies or stamps not accepted)

6/10/24

Date

Board Use Only	Date Received: 7/23/24	Amount: $50 - ck 1095737321

06/25/2024

To: Nevada State Board of Pharmacy

My name is Nicole Brooks and I am currently attending the Pharmacy Technician program at Northwest Career College in Las Vegas, NV. I am writing to provide details about my background charges that I was convicted of in 2005.

During my early twenties, I was experiencing some challenges. Both of my very young children were with their Grandmother and I was in between houses experiencing homelessness. I was trying to figure it out for my children and focus on what I needed to do. I thought that I had found my person to go through life with, that was going to continue to create a future with, my boyfriend at the time. My boyfriend at the time, he was very sweet, supportive and I thought he was a great guy. That was until the night that my whole life changed.

He told me that he had some friends coming into town and asked if I could go and get a hotel room for them before they got there, he gave me the money, but I put the room under my name, not thinking anything of it, why would I not trust the person that I was going to build a future with. However, I spent about 10 minutes with him and his "friends" when they got there and immediately thought these are not the type of people I want to be around. I left with my boyfriend and was gone for about an hour and went to go back to check on the room since I just had a weird feeling. I went over there by myself, I was there for about 10 minutes, trying to figure out these people and how they could know my boyfriend. Within that 10 minutes, there is a loud knock on the door. The Police surrounded the room.

On the evening of February 25, 2005, as I sit in a room in my name, around people that I don't really know, Police surround the room, in the front door and on the back patio. Not known to me was that the Police were called by one of the individuals mother's. While I was gone for that hour, a female and two males in that room robbed someone for large amounts of Marijuana and the guy that was robbed, found the females house and told her mother that her daughter was going to get killed. Her mother, in a panic, called the police and sent them to the hotel room. While I didn't know that was happening, what I did know is that more than 10 police officers came into the room and I am surrounded wondering what is happening. The two men run to the bathroom and lock themselves in and I am taken to the hallway, I am crying, anxiety going through me and throwing up. I have never been in trouble before and now I sit in a hotel hallway surrounded by police as they ask me what is going on because my name is on the room. Police proceed to take out scales, drugs and guns. I also find out that the female that was there was underage. I was in shock, how could my good deed of trying to help out my boyfriends friends end up with me being taken to jail, but that is exactly what happened. I stayed in jail for 5 days, went to court and the judge stated that they needed to release me or charge me. I was released on bond and called my father and begged him to come and get me.

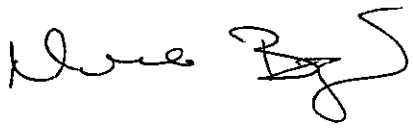
My dad took me back to Missouri, I got my children, and continued working, now focusing on my future without the person that I thought would have my back. The only time that I went back to Kansas, was to turn myself in, making sure that this was closed and didn't have to worry about it in the future. When I did this, they put me on probation for just about 2 months, I had to pay some fines and after that, I continued about my life, focusing on what I needed to do for myself and my children.

That night deeply impacted me and changed my life. Since then, I have worked at the hospital as a cook, have been in professional settings and have never been in trouble again. I've been fingerprinted, had background checks and to this day, tell my children (that are grown) don't EVER get someone a hotel room, car, anything, because you never know what will happen by just trying to be nice and help someone

out. I tell them to trust their instincts, because now in my forties, and never have been in trouble since, I focus on how to help my children ensure they are never put in that situation.

Currently, I am still a chef, I've been in Las Vegas for 3 years, I've been with my husband for 8 years and we have 4 children combined, 4 high school graduates and 2 College graduates, one that is going back to get their Masters degree while teaching High School English, my other child that is going to Law School for Real Estate Law, and my other children focusing on their careers. I am so proud of them, they have never been in trouble, they are amazing kids and having had the chance to watch them grow, now it's the chance for me to continue to grow as well. I've wanted the chance to work in the pharmacy world for years, having come to Northwest Career College, gave me the chance to focus on now my education. I had the chance to work in a pharmacy about 15 years ago, during that time, I fell in love with the world of pharmacy. Being able to put a smile on the faces of patients, even if they were having a bad day, I had the chance to make a change, help someone and hopefully be the reason for someone to have a great day. Working in the pharmacy wasn't a job to me, it was a career that I loved and something I was passionate about. Since then, I have worked a few jobs but they have always been jobs, I want to go back to that feeling that I got working in the pharmacy and it is my dream to be able to continue moving forward. I promise that I will continue to make a positive difference to my family, myself and my community.

Thank you for considering me,



Nicole Brooks

Public Portal Access Criminal

Case Summary

Case No. [redacted]

State of Kansas vs. Nicole S. Brooks	§	Location:	**Leavenworth County**
	§	Judicial Officer:	**Sundby, Gunnar**
	§	Filed on:	**03/11/2005**
	§	Appear by:	**03/12/2005**

Case Information

Case Type: CR Felony
Case Status: **06/30/2005 Disposed**

Offense

1. Possession of opiates, opium or narcotic drugs

Statute	Degree	Offense Date	Filed Date
65.4160	FEDO	02/25/2005	03/11/2005

Offense Reports
Agency: Leavenworth Police Department
Leavenworth, KS, 66048

Filed As: Sale etc. of opiates, opium or narcotic drugs
Original Statute: 65.4161
Original Degree: FEDO
Amended Date: 04/10/2009

2. Sale, offer depressnts/hallucin/stimulants/anabolic steroids

Statute	Degree	Offense Date	Filed Date
65.4163.A	FEDO	02/25/2005	03/11/2005

Offense Reports
Agency: Leavenworth Police Department
Leavenworth, KS, 66048

3. Poss simulated controlled substances or drug paraphernalia

Statute	Degree	Offense Date	Filed Date
65.4152	MDA	02/25/2005	03/11/2005

Offense Reports
Agency: Leavenworth Police Department
Leavenworth, KS, 66048

4. Taxation; Drugs; Evidence of tax payment

Statute	Degree	Offense Date	Filed Date
79.5204	FE10	02/25/2005	03/11/2005

Offense Reports
Agency: Leavenworth Police Department
Leavenworth, KS, 66048

5. Criminal use of weapons; Carrying firearm concealed on one's person

Statute	Degree	Offense Date	Filed Date
21.4201.A.4	MDA	02/25/2005	03/11/2005

Offense Reports
Agency: Leavenworth Police Department
Leavenworth, KS, 66048

6. Contributing to a child's misconduct; To commit misdemeanor, etc

Statute	Degree	Offense Date	Filed Date
21.3612.A.2	MDA	02/25/2005	03/11/2005

Offense Reports
Agency: Leavenworth Police Department
Leavenworth, KS, 66048

Statistical Closures

06/15/2005 Other

Bonds

Surety

#[redacted]
$15,000.00
06/04/2014
Posted
02/18/2015
Closed
Counts: 1

Personal Recognizance

#[redacted]
$5,000.00
06/05/2014
Closed
03/12/2010
Posted
Counts: 1

Personal Recognizance

#[redacted]
$10,000.00
06/05/2014
Closed

04/10/2009
Posted
Counts: 1

Personal Recognizance
#[redacted]
$50,000.00
06/05/2014
Closed
03/07/2005
Posted
Counts: 1
Comments:
NO CONTACT WITH Zane Narramore and Ashley Colbert

Party Information

Prosecutor	**State of Kansas**	**Bryant, John James** ***Retained***
Defendant	**Brooks, Nicole Shriee**	**Snider, Debra D.** ***Court Appointed***
		Hollins, H. Kent ***Retained*** ~~*Caprice, Kiann (Inactive)*~~ ~~*Court Appointed*~~

Dispositions

04/10/2009 **Plea**
Brooks, Nicole Shriee
1. Possession of opiates, opium or narcotic drugs
Guilty
TRN: TRS: 1

04/10/2009 **Disposition**
1. Possession of opiates, opium or narcotic drugs
Guilty Plea
TRS: 1

04/10/2009 **Disposition**
Collections date 10-28-13...removed from collections 6-24-14
2. Sale, offer depressnts/hallucin/stimulants/anabolic steroids
Dismissal
TRS: 2

04/10/2009 **Disposition**
Collections date 10-28-13...removed from collections 6-24-14
3. Poss simulated controlled substances or drug paraphernalia
Dismissal
TRS: 3

04/10/2009 **Disposition**
Collections date 10-28-13...removed from collections 6-24-14
4. Taxation; Drugs; Evidence of tax payment
Dismissal
TRS: 4

04/10/2009 **Disposition**
Collections date 10-28-13...removed from collections 6-24-14
5. Criminal use of weapons; Carrying firearm concealed on one's person
Dismissal
TRS: 5

04/10/2009 **Disposition**
Collections date 10-28-13...removed from collections 6-24-14
6. Contributing to a child's misconduct; To commit misdemeanor, etc
Dismissal
TRS: 6

Case Events

02/28/2005 Hearing Scheduled
Hearing Scheduled (First Appearance 02/28/2005 09:00 AM)

02/28/2005
Continued
Hearing result for First Appearance held on 02/28/2005 09:00 AM: Df app. Continued to 3/7 @ 10. Bond screen ordered.

03/07/2005 Hearing Scheduled
Hearing Scheduled (Appearance 03/07/2005 09:00 AM)

03/07/2005
Hearing Held
Hearing result for Appearance held on 03/07/2005 09:00 AM: Df app, to be released if no charges filed by 12:01.

03/08/2005
Own Recognizance Bond
Own Recognizance Bond (Amount 50000.00) Document title: SURETY-RECOGNIZANCE BOND Document # 140835 indexed to this case

03/08/2005
Conditions of Bond
Conditions of Bond NO CONTACT WITH Zane Narramore and Ashley Colbert Document title: CONDITIONS OF BOND Document # 140851 indexed to this case

03/11/2005
The record of all proceedings in this case were taken by Jo
The record of all proceedings in this case are taken by Estella Caballero CSR, unless otherwise noted.

03/11/2005
Complaint/Information
COMPLAINT/INFORMATION filed Document title: COMPLAINT/INFORMATION Document # 140838 indexed to this case

03/11/2005
Affidavit
ARREST/DETENTION PROBABLE CAUSE AFFIDAVIT filed Document title: ARREST/DETENTION PROBABLE CAUSE AFFIDAVIT Document # 140840 indexed to this case

03/24/2005
Application for Court Appointed Attorney
APPLICATION FOR APPOINTED DEFENSE SERVICES / FINANCIAL AFFIDAVIT filed Document title: APPLICATION FOR APPOINTED DEFENSE SERVICES/FINANCIAL AFFIDAV Document # 140847 indexed to this case

01/06/2009 Judge: Normal Case flow
Judge: Normal Caseflow (batch process)

02/09/2009 Hearing Scheduled
Hearing Scheduled (Bench Warrant Hearing 02/09/2009 09:00 AM)

02/09/2009
Continued

Hearing result for Bench Warrant Hearing held on 02/09/2009 09:00 AM: State by JBryant; Defendant in custody; Apoint attorney; Continue to 2/11/09 at 9am for Appearance with attorney; Bond screen ordered

02/09/2009 Hearing Scheduled

Hearing Scheduled (Appearance with Attorney 02/11/2009 09:00 AM)

02/09/2009
Default Conversion ROA

Email Sent Date: 02/09/2009 10:34 am To: KiAnn McBratney (kiannmcbratney@yahoo.com) No Files Attached.

02/09/2009
Order

Order Document title: ORDER APPOINTING COUNSEL PRIVATE OR PUBLIC DEFENDER - K McBratney Document # 318428 indexed to this case

02/10/2009
Application

Application Document title: APPLICATION FOR APPOINTED DEFENSE SERVICES/FINANCIAL AFFIDAVIT Document # 318510 indexed to this case

02/10/2009
Bench Warrant Returned - Served

BENCH WARRANT returned served Failure to Appear Defendant: Brooks, Nicole S Document title: BENCH WARRANT served 02-08-09 Document # 318541 indexed to this case

02/11/2009
Hearing Held

Hearing result for Appearance with Attorney held on 02/11/2009 09:00 AM: State by JBryant; Defendant in custody and by KMcBratney; Continue to 2/18/09 at 1pm for Preliminary

02/11/2009 Hearing Scheduled

Hearing Scheduled (Preliminary 02/18/2009 01:00 PM)

02/11/2009
Default Conversion ROA
Email Sent Date: 02/11/2009 03:13 pm To: KiAnn McBratney (kiannmcbratney@yahoo.com) File Attached: jenniferb_e4.pdf Name of Document: ORDER APPOINTING COUNSEL PRIVATE OR PUBLIC DEFENDER

02/11/2009
Bond
Bond Document title: BOND SCREEN REPORT Document # 319175 indexed to this case

02/11/2009 Subpoena
Witness: Parker, Ryan; Witness Type: For Complainant;

02/11/2009
Subpoena issued
SUBPOENA issued Ryan Parker 2-18-09 1pm Wyandotte County Document title: SUBPOENA issued Ryan Parker Document # 319236 indexed to this case

02/13/2009
Withdrawal
Withdrawal Document title: WITHDRAWAL OF BENCH WARRANT Document # 321183 indexed to this case

02/17/2009
Default Conversion ROA
Email Sent Date: 02/17/2009 02:36 pm To: fscopy File Attached: jenniferb_e17.pdf Name of Document: WITHDRAWAL OF BENCH WARRANT

02/18/2009
Preliminary Hearing Held
Hearing result for Preliminary held on 02/18/2009 01:00 PM: State by JBryant; Defendant in custody and by KMcBratney; Preliminary Hearing Held; Probable cause found on Counts 1, 2,3, 5,6 - boundover for Arraignment; Dismiss Count 4; Arraignment held - plead not guilty; Set Pretrial Conference on 3/13/09 at 11am

02/18/2009 Hearing Scheduled
Hearing Scheduled (Pretrial Conference 03/13/2009 11:00 AM)

02/18/2009 Hearing Scheduled
Hearing Scheduled (Hearing 02/18/2009 01:00 PM) Continued

02/18/2009
Hearing Held
*Hearing result for Hearing held on 02/18/2009 01:00 PM: ***LATER *** Bond reduced to $2,500 c/s*

02/24/2009
Transcript
Transcript Document title: TRANSCRIPT of PRELIMINARY HEARING held on February 18, 2009 - transcribed by Larry Thibault, CSR Document # 325913 indexed to this case

02/24/2009
Subpoena Served/Returned
SUBPOENA served Ryan Parker 2-17-09 agent Wyandotte County Sheriff Document title: SUBPOENA Served Ryan Parker Document # 326048 indexed to this case

02/26/2009
Notice
Notice Document title: NOTICE AND ORDER OF PRE-TRIAL CONFERENCE Document # 328648 indexed to this case

03/02/2009
Default Conversion ROA
Email Sent Date: 03/02/2009 03:19 pm To: fscopy File Attached: alician_e7.pdf Name of Document: NOTICE AND ORDER OF PRE-TRIAL CONFERENCE

03/13/2009
Continued
Hearing result for Pretrial Conference held on 03/13/2009 11:00 AM: State by JBryant; Defendant in custody; KMcBratney out ill; Continue to 3/27/09 at 2pm for Pretrial Conference

03/13/2009 Hearing Scheduled
Hearing Scheduled (Pretrial Conference 03/27/2009 02:00 PM)

03/20/2009
Withdrawal
Withdrawal Document title: WITHDRAWAL OF BENCH WARRANT Document # 342302 indexed to this case

03/27/2009
Default Conversion ROA
Email Sent Date: 03/27/2009 02:11 pm To: fscopy File Attached: jenniferb_e3.pdf Name of Document: WITHDRAWAL OF BENCH WARRANT

03/27/2009
Pretrial Conference Held
Hearing result for Pretrial Conference held on 03/27/2009 02:00 PM: State by JBryant; Defendant in custody and by KMcBratney; Pretrial Conference Held; Set for Jury Trial for 5/4/09 at 9am (1 1/2 days)

03/27/2009 Hearing Scheduled
- *Hearing Scheduled (Jury Trial 05/04/2009 09:00 AM)*

03/30/2009 Hearing Scheduled
Hearing Scheduled (Motion 04/03/2009 09:00 AM)

03/31/2009
Motion
Motion Document title: MOTION TO DETERMINE THE ADMISSIBLITY OF EVIDENCE Document # 343908 indexed to this case

03/31/2009
Default Conversion ROA
Email Sent Date: 03/31/2009 11:57 am To: CAO - f/s copy (fscopy@leavenworthcounty.org) and KiAnn McBratney (kiannmcbratney@yahoo.com) File Attached: jenniferb_e31.pdf Name of Document: MOTION TO DETERMINE THE ADMISSIBLITY OF EVIDENCE

03/31/2009 Subpoena
Witness: KBI Chemist, ; Witness Type: For Complainant;

03/31/2009
Subpoena issued
SUBPOENA Issued KBI Chemist 05-04-09 1pm CAO Document title: SUBPOENA Issued KBI Chemist Document # 346795 indexed to this case

03/31/2009 Subpoena
Officer: Cavazos, Pedro, LVPD; Subpoena Served

03/31/2009 Subpoena
Officer: Warren, Dale, LVPD; Subpoena Returned, not served LVPD;

03/31/2009 Subpoena
Officer: Inman-Brandau, Shannon, LVPD; Subpoena Served

03/31/2009
Subpoena issued
SUBPOENA Issued Brandau, Shannon 05-04-09 1pm LVSO Document title: SUBPOENA Issued Shannon Brandau Document # 346812 indexed to this case

03/31/2009
Subpoena issued
SUBPOENA Issued Cavazos,Pedro 05-04-09 1pm LVSO Document title: SUBPOENA Issued Pedro Cavazos Document # 346815 indexed to this case

1-50 of 194

Financial Information

	Defendant Brooks, Nicole Shriee		
	Total Financial Assessment		1,449.20
	Total Payments and Credits		1,449.20
	Balance Due as of 06/20/2024		**0.00**
05/20/2009	Transaction Assessment		0.00
05/20/2009	Transaction Assessment		129.50
05/20/2009	Transaction Assessment		7.00
05/20/2009	Transaction Assessment		9.00
05/20/2009	Transaction Assessment		1.00
05/20/2009	Transaction Assessment		0.50
05/20/2009	Transaction Assessment		400.00
05/20/2009	Transaction Assessment		50.00
05/20/2009	Transaction Assessment		100.00
06/21/2009	Case Payment	Receipt # 109848	(10.00)
06/25/2009	Transaction Assessment		73.72
08/03/2009	Case Payment	Receipt # 112071	(10.00)

09/29/2009	Case Payment	Receipt # 114942	(30.00)
06/15/2010	Adjustment		18.18
06/15/2010	Adjustment		(18.18)
06/15/2010	Adjustment		18.18
07/08/2014	Transaction Assessment		100.00
07/08/2014	Case Payment Craig Reynolds	Receipt # 196640	(100.00)
07/20/2014	Transaction Assessment		35.00
07/20/2014	Case Payment Craig Reynolds	Receipt # 197118	(-100.00)
07/24/2014	Transaction Assessment		30.00
07/24/2014	Case Payment	Receipt # 197287	(160.00)
08/26/2014	Case Payment	Receipt # 198597	(20.00)
09/01/2014	Adjustment		(30.00)
09/01/2014	Case Payment	Receipt # 198734	(-160.00)
09/01/2014	Case Payment	Receipt # 198737	(-20.00)
09/01/2014	Case Payment	Receipt # 198739	(160.00)
09/01/2014	Case Payment	Receipt # 198740	(20.00)
09/09/2014	Case Payment	Receipt # 199147	(20.00)
09/23/2014	Adjustment		500.00
12/04/2014	Adjustment		25.30
09/02/2015	Case Payment	Receipt # 212699	(500.00)
06/13/2017	Case Payment CBK	Receipt # 237592	(124.85)
06/13/2017	Case Payment CBK	Receipt # 237593	(134.13)
09/12/2017	Case Payment CBK	Receipt # 241287	(117.70)

09/12/2017	Case Payment CBK	Receipt # 241288	(31.45)
10/17/2017	Case Payment CBK	Receipt # 242626	(129.94)
10/17/2017	Case Payment CBK	Receipt # 242627	(161.13)

19

19A

PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY

LCB FILE NO. R085-24I

The following document is the initial draft regulation proposed by the agency submitted on 04/24/2024

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop – April 18, 2024

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[~~omitted material~~]** is material to be omitted. and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: § 1, NRS 639.070, 639.266

A REGULATION relating to pharmacy; clarifying record keeping requirements of counseling by a pharmacy; and providing other matters properly relating thereto.

NAC 639.708 of NAC is hereby amended to read as follows:

NAC 639.708 **Counseling of patients: Duties of pharmacy**. (NRS 639.070, 639.266) To facilitate counseling regarding a prescription, a pharmacy shall:

1. Maintain a record of medication for each patient to whom a prescription has been dispensed by that pharmacy. The record must:
   (a) Be retrievable for use by the pharmacist;
   (b) Be maintained for at least 2 years after the most recent entry;
   (c) List all prescriptions dispensed to the patient at that pharmacy; and
   (d) Include all data required to be placed on the prescription.
2. Make a reasonable effort to obtain and retain in the record of medication the:
   (a) Telephone number or numbers, if any, of the patient;
   (b) Gender of the patient;
   (c) Age or date of birth of the patient;
   (d) History of the patient, including allergies, reactions to particular drugs and any medications or medical devices used by the patient; and
   (e) Any comments relevant to the drug therapy of the patient, including any other information which is specific to the patient or drug.
3. Ensure that a pharmacist is available by telephone during business hours and, if the pharmacy routinely delivers prescriptions outside of the trade area covered by local telephone service, provide a toll-free telephone number.

4. Include with each prescription container delivered or distributed by a public carrier:
    (a) The local, and if applicable toll-free, telephone numbers of the pharmacy;
    (b) The hours during which the patient may contact the pharmacy by telephone; and
    (c) A written notice in substantially the following form:

Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available between the hours of ..... and ..... to answer your questions.

5. Maintain the confidentiality of each patient's records, including prescriptions, pursuant to NRS 639.238. A pharmacist shall not divulge the contents of a patient's records, except as authorized by NRS 639.238.
6. Make available to a practitioner, upon request, all information relating to a prescription that is provided to a patient of that practitioner by the pharmacist or an intern pharmacist.
7. Ensure that counseling is conducted in a confidential manner to prevent disclosure of information to any person other than the patient or the person caring for the patient.
8. ***Maintain a readily retrievable record of patient counseling for each prescription that is required of a pharmacist or intern pharmacist pursuant to NAC 639.707. In addition to the record requirements pursuant to NAC 639.707 subsection 6, the record must also include:***
    (a) The date and time the prescription was dispensed;
    (b) The prescription number;
    (c) The date counseling was provided to or refused by a patient or the person caring for the patient; and
    (d) Whether counseling was given or whether counseling was affirmatively refused by the patient for all new prescriptions or prescriptions that require counseling.
9. ***A pharmacy must keep accurate records of patient counseling.***
10. ***A pharmacy has a duty to staff a pharmacy in a manner that allows for adequate counseling of patients.***

REVISED PROPOSED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R085-24

June 25, 2024

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§ 1 and 2, NRS 639.070 and 639.266.

A REGULATION relating to pharmacy; revising requirements concerning the documentation of the counseling of a patient by a pharmacist, intern pharmacist or dispensing practitioner; requiring a pharmacy or dispensing practitioner to have certain staff; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires a pharmacist, upon receiving a prescription and after reviewing the record of the patient, to communicate with the patient or a person caring for the patient matters which will enhance therapy through drugs. Existing law requires such communication to include appropriate elements of counseling, as prescribed by regulations of the State Board of Pharmacy. (NRS 639.266) **Section 2** of this regulation requires a pharmacy or dispensing practitioner to ensure that the pharmacy or dispensing practitioner, as applicable, has adequate staff to comply with all legal requirements governing the counseling of patients.

Existing regulations require a pharmacy or dispensing practitioner to maintain a record of medication for each person to whom a prescription has been dispensed by the pharmacy or dispensing practitioner, as applicable. (NAC 639.708) **Section 2** requires such a record to include: (1) the prescription number; (2) the date and time that the prescription was dispensed; and (3) certain information about counseling provided to the patient or the refusal of the patient to accept such counseling. **Section 1** of this regulation requires a pharmacist, intern pharmacist or dispensing practitioner who dispenses a prescription to: (1) create or update, as applicable, the record of medication; and (2) include the record of medication in the computerized system or files of the pharmacy. **Section 1** also removes an existing requirement that is partially duplicative of the requirements being added by **section 2**.

Section 1. NAC 639.707 is hereby amended to read as follows:

639.707 1. Except as otherwise provided in this section, a pharmacist, an intern pharmacist under the supervision of a pharmacist or a dispensing practitioner shall verbally

provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient that:

(a) Has not been previously dispensed to the patient from that pharmacy or dispensing practitioner, as applicable; or

(b) Has been previously dispensed to the patient from that pharmacy or dispensing practitioner, as applicable, including, without limitation, a prescription drug or a device that is being refilled, if, in the professional judgment of the pharmacist, intern pharmacist or dispensing practitioner:

(1) The information would further or improve the drug therapy of the patient; or

(2) A reasonable concern relating to the safety or efficacy of the drug therapy of the patient was raised by the review of the patient's record that the pharmacist, intern pharmacist or dispensing practitioner conducted pursuant to subsection 4.

2. The information provided by the pharmacist, intern pharmacist or dispensing practitioner pursuant to subsection 1 may include, without limitation:

(a) The name and a description of the drug;

(b) The form of dosage, dose, route of administration and duration of drug therapy;

(c) The intended use of the drug or device and expected responses from that use;

(d) Any special directions and precautions for the preparation, administration and use of the drug or device by the patient;

(e) Any common severe side effects, interactions and contraindications that may occur, recommendations to avoid these side effects, interactions or contraindications, and the action required if they occur;

(f) Techniques for the patient or the person caring for the patient to monitor the drug therapy;

(g) Proper storage of the drug or device;

(h) Information about refilling the prescription;

(i) Actions to be taken in the event of a missed dose;

(j) Any relevant information contained in the record of medication of the patient; and

(k) Any other information which, in the professional judgment of the pharmacist, intern pharmacist or dispensing practitioner, is necessary to ensure the safe and effective use of the drug or device by the patient.

3. The pharmacist or intern pharmacist shall provide the information required pursuant to subsections 1 and 2 in written form to the patient if a drug or device will be distributed to the patient outside the confines of the pharmacy by mail or any other delivery service. A pharmacist or intern pharmacist is not required to provide written information pursuant to this subsection if the drug or device is being delivered to a patient who is in a licensed medical facility where other licensed health care professionals are authorized to administer drugs.

4. The pharmacist, intern pharmacist or dispensing practitioner shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation:

(a) Overutilization of the drug and drug misuse;

(b) Underutilization of the drug;

(c) Therapeutic duplications, contraindications and any warning labels or other information included with the drug;

(d) Interactions between the drug and any:

(1) Other drugs which the patient is taking or has recently taken;

(2) Diseases which the patient has, including any stages of that disease; and

(3) Allergies that the patient may have; and

(e) Incorrect dosage or duration of treatment.

5. A pharmacist, intern pharmacist or dispensing practitioner is not required to counsel a patient pursuant to this section if the patient or a person caring for the patient refuses to accept the counseling.

6. ~~[Except as otherwise provided in subsection 7, the]~~ ***A*** pharmacist, intern pharmacist or dispensing practitioner ***who dispenses a prescription*** shall ~~[, at the time that counseling is provided or refused:~~

~~(a) Initial a written document that is maintained at the pharmacy or at the primary place of business of the dispensing practitioner to record whether counseling was provided to or refused by a patient or the person caring for the patient; or~~

~~(b) Enter, pursuant to NAC 639.751, initials onto a record in a computerized system used by the pharmacy or dispensing practitioner, as applicable, for recording information concerning prescriptions to indicate whether counseling was provided to or refused by a patient or the person caring for the patient.~~

~~7. The pharmacist, intern pharmacist or dispensing practitioner is not required to comply with the provisions of subsection 6 if the prescription drug or device dispensed to the patient is being refilled.]~~ ***:***

(a) Create or update, as applicable, the record of medication described in subsection 1 of NAC 639.708; and

(b) Include the record of medication, and any updates to the record of medication, in the computerized system or files, as applicable, of the pharmacy where the prescription is dispensed.

Sec. 2. NAC 639.708 is hereby amended to read as follows:

639.708 To facilitate counseling regarding a prescription, a pharmacy or dispensing practitioner shall:

1. Maintain a record of medication for each patient to whom a prescription has been dispensed by that pharmacy or dispensing practitioner, as applicable. The record must:

(a) Be retrievable for use by the pharmacist or dispensing practitioner;

(b) Be maintained for at least 2 years after the most recent entry;

(c) List all prescriptions dispensed to the patient at that pharmacy or by the dispensing practitioner; and

(d) Include ~~[all]~~ ***for each prescription dispensed at the pharmacy or by the dispensing practitioner:***

(1) All data required to be placed on the prescription ~~[.]~~ ***;***

(2) The prescription number;

(3) The date and time on which the prescription was dispensed; and

(4) If counseling is required by NAC 639.707:

(I) A notation of whether such counseling was provided by a pharmacist, intern pharmacist or dispensing practitioner or refused by the patient or a person caring for the patient that is made at the time the counseling was provided or refused and initialed by the pharmacist, intern pharmacist or dispensing practitioner who provided or offered to provide the counseling; and

(II) The date on which the counseling was provided or refused, as applicable.

2. Make a reasonable effort to obtain and retain in the record of medication the:

(a) Telephone number or numbers, if any, of the patient;

(b) Gender of the patient;

(c) Age or date of birth of the patient;

(d) History of the patient, including allergies, reactions to particular drugs and any medications or medical devices used by the patient; and

(e) Any comments relevant to the drug therapy of the patient, including any other information which is specific to the patient or drug.

3. Ensure that a pharmacist or dispensing practitioner who has access to the medical records of the patient is available by telephone during business hours and, for a pharmacy that routinely delivers prescriptions outside of the trade area covered by local telephone service, provide a toll-free telephone number.

4. Include with each prescription container of a pharmacy that is delivered or distributed by a public carrier:

(a) The local, and if applicable toll-free, telephone numbers of the pharmacy;

(b) The hours during which the patient may contact the pharmacy by telephone; and

(c) A written notice in substantially the following form:

> Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available between the hours of ..... and ..... to answer your questions.

5. Maintain the confidentiality of each patient's records, including prescriptions, pursuant to NRS 449A.112 or 639.238, as applicable. A pharmacist or dispensing practitioner shall not

divulge the contents of a patient's records, except as authorized by NRS 639.238 or any other applicable provision of law.

6. Make available to a practitioner, upon request, all information relating to a prescription that is provided to a patient of that practitioner by the pharmacist, an intern pharmacist or a dispensing practitioner.

7. Ensure that counseling is conducted in a confidential manner to prevent disclosure of information to any person other than the patient or the person caring for the patient.

8. Ensure that the pharmacy or dispensing practitioner has adequate staff to comply with the requirements of this section, NAC 639.707 and any other requirements of federal or state law or the regulations of the Board regarding the counseling of patients.

20

21

Executive Secretary Report

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Licensing Update
H. 2025 Nevada Board of Pharmacy Yearly Calendar

September 2024 Temporary License since last Board Meeting

Name	License Type
Laci Quick	Pharmacist
Robert Ordoyan	Pharmacist
Timothy Ivers	Pharmacist
Rajendra Mishra	Pharmacist
Joshua Hevener	Pharmacist
Tara O'Connell	Pharmacist
Trate DeVolld	Pharmacist
Alexandra Spektor	Pharmacist

September 2024 – NV Business Address Change Only

Application Received	Business Name	License Number	New Location	City, State and Zip
8/13/2024	CPAP & More	MP00796	621 Pyramid Way	Sparks, NV 89431

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.870: APRN Dispensing License/pharmacy applicant appearance	06/02/22	06/02/22 – Dave revising language.	R086-22	06/29/22; 07/05/22: under Dave review; 10/12/23: Included in R100-23 (Executive Order Regs)				
NAC 453.310: DEA Registration	10/13/22	10/19/22	R197-22	05/12/23: to Dave/ Yenh; 05/26/23: Under review by Yenh/Peter; 05/30/23: Hold till final rule on state specific DEA registration requirement.	11/02/23	12/07/23	12/22/23	2/27/24
NAC 639.694: DME Administrator for DME Inventory at a Licensed Hospital	09/07/23	09/12/23	R058-23	10/09/23	11/02/23	12/07/23	12/22/23	2/27/24

NAC 639.520: Security of Pharmacies	09/07/23 Dave to meet with industry							
NAC 639: Administrative Fine in Lieu of Disciplinary Action	09/07/23	09/12/23	R057-23	10/09/23	11/02/23	12/07/23	12/22/23	2/27/24
NAC 639: Protocol for RPH to Treat OUD (AB156)	09/07/23	09/12/23	R059-23	10/19/23	11/02/23	12/07/23	12/22/23	2/27/24
Regulations relating to Governor Lombardo's Executive Order 003-2023. Changes in these Regulations streamline and clarify licensing requirements while ensuring public safety; and providing other matters properly relating thereto.	10/11/23	10/18/23	R100-23	3/6/24	3/14/24; 4/9/24	5/30/24	4/18/24 - Early Review Sent Inform and SBIMPACT to LCB 6/6/24	6/14/24
NAC 453: The proposed amendments relate to controlled substances adding synthetic cannabinoids to the controlled substances listed in Schedule I.	10/11/23	10/18/23	R101-23	11/08/23 - To Dave/ Yenh for review.	3/14/24	4/18/24	4/25/24	6/20/24
NAC 453: Add Zuranolone to Schedule IV	12/07/23	12/13/23	R144-23	01/03/24	2/6/24	3/7/24	3/18/24	4/19/24

NAC 639: The proposed amendment ensures proper and adequate safeguards for registered nurses who participate in certain public health programs or certain mental health services.	01/18/24	2/6/24	R013-24	2/26/24	3/14/24; 4/9/24	5/30/24	4/18/24 - Early Review Sent Inform and SBIMPACT to LCB 6/10/24	6/14/24
NAC 639: The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standards.	01/18/24 03/07/24	3/12/24	R053-24	5/13/24 – To Dave/Yenh for review	6/18/24	7/18/24: Dave to make revisions with LCB		
NAC 453: The proposed amendments relate to controlled substances adding tianeptine, hallucinogenic substances and fentanyl related substances to the controlled substances listed in Schedule I.	3/7/24	3/12/24	R054-24	4/1/24	4/9/24	5/30/24	6/6/24	6/20/24

A REGULATION relating to pressurized stocking. Allowing pressurized stocking to be provided without a prescription in certain circumstances.	3/7/24	3/12/24	R052-24	4/1/24	4/9/24	5/30/24	6/10/24	6/20/24
The proposed amendments establishes the registration requirements for certified registered nurse anesthetist, under the supervision of a physician licensed pursuant to chapter 630 or 633 or NRS, to order, prescribe, possess, and administer controlled substances, poisons, dangerous drugs and devices to treat a patient under the care of a licensed physician in a critical access hospital in preparation for surgery or childbirth, during surgery or childbirth and while a patient recovers from surgery or childbirth.	3/7/24	3/12/24	R051-24	4/10/24	4/24/24	5/30/24	6/10/24	6/20/24
Amendment to Nevada Administrative Code (NAC) 639.708. The proposed amendments clarifies record keeping requirements of counseling by a pharmacy.	4/18/24	4/23/24	R085-24	6/03/24 – To Dave/Yenh for Review 6/25/24 – Sent revised version to Yenh/Dave	7/19/24	09/05/24		

Amendment to Nevada Administrative Code (NAC). The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise.	5/29/24	6/3/24	R113-24	6/25/24 – To Yenh/Dave for review 7/15/24 – sent revised version to Dave/Yenh				
Amendment to Nevada Administrative Code NAC 639.748. The proposed amendments revises the requirements concerning the documentation an employee of a pharmacy must obtain from a person before dispensing a controlled substance pursuant to a lawful prescription to the person. **(FOR POSSIBLE ACTION)**	7/18/24	7/19/24	R189-24	7/30/24		10/17/24		

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 2**
  - **Other: 1**
- **Citation & Fine –**
  - **Unlicensed Practice:**
  - **Misfill:**
  - **Other: 3**

2025
Nevada Board of Pharmacy Calendar

January						
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February						
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September						
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BOARD MEETING DATES	
Jan 15-16	Las Vegas, NV
March 5-6	Las Vegas, NV
April 16-17	Reno, NV
June 4-5	Las Vegas, NV
July 16-17	Reno, NV
Sep 10-11	Las Vegas, NV
Oct 15-16	Las Vegas, NV
Dec 3-4	Las Vegas, NV

OBSERVED STATE HOLIDAYS	
Jan 01	New Years Day
Jan 20	Martin Luther King, Jr.'s Birthday
Feb 17	Washington's Birthday
May 26	Memorial Day
Jun 19	Juneteenth Day
Jul 04	Independence Day
Sept 1	Labor Day
Oct 31	Nevada Day
Nov 11	Veterans' Day
Nov 27	Thanksgiving Day
Nov 28	Family Day
Dec 25	Christimas Day

ANNUAL MEETINGS	
APhA Annual	March 21-24 (Nashville, TN)
NACDS Annual	April 26-29 (Palm Beach, FL)
NABP Annual	May 13-16 (Fort Lauderdale, FL)
ASHP Summer	June 7-11 (Charlotte, NC)
NASCSA Annual	October 20-23 (New Orleans, Louisiana)
ASHP Mid Year	December 7-11 (Las Vegas, NV)
NABP District 8	TBD

22

23

24