SUMMARY SUSPENSION/NOTICE OF OPPORTUNITY FOR HEARING
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE

IN THE MATTER OF: **CASE NO. A-2025-0351**

Luxe Laser **License No. 02-2395550**
c/o Wade Banker
1500 Holland Rd.
Maumee, OH 43537

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 11/4/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

November 4, 2025

Dear Luxe Laser and Wade Banker

You are hereby notified, in accordance with Section 119.07 of the Ohio Revised Code (ORC), the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Luxe Laser's license as a Terminal Distributor of Dangerous Drugs (TDDD) under authority of Sections 4729.57 and 4729.571 of the Ohio Revised Code.

Furthermore, the Board finds that based upon the facts set forth in the Allegations Section, there is clear and convincing evidence of a danger of immediate and serious harm to others due to Luxe Laser's method used to possess or distribute dangerous drugs. As such, the Board summarily suspends Luxe Laser's license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Sections 4729.54 and 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Further, pursuant to Section 4729.55(E), the Board shall refuse to issue a future license to an applicant for a TDDD if the applicant, or any agent (including any owner or responsible person) or employee of the applicant, has been found to have violated any of the specified laws identified therein or any rule of the board, absent proof of adequate safeguards assuring prevention of a recurrence of the violation. Additionally, Section 4729.57 of the Ohio Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or $1,000 if the acts committed have not been classified as an offense by the ORC.

2. Pursuant to Section 4729.571(A)(1) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method used by the terminal distributor to possess or distribute dangerous drugs

3. Luxe Laser, located at 1500 Holland Rd., Maumee, Ohio 43537, is a clinic licensed by the Board (TDDD 02-2395550). The clinic is owned by Wade Banker [Permanently Revoked Ohio Medical Board license number 35.074019] and lists Shazeeda Bakhsh, APRN [Ohio Nursing Board license number APRN.CNP.026118] as the Responsible Person.

ALLEGATIONS

1. On or about October 21, 2025, the Board conducted an inspection at Luxe Laser, a wellness clinic licensed by the Board (TDDD 02-2395550). The clinic employees one nurse practitioner, one registered nurse, and front office personnel. Owner Wade Banker and Responsible Person APRN Shazeeda Bakhsh were present during the inspection.

2. Multiple warnings requiring written responses were issued for violations, including the following:

    a. The clinic obtained illegal GLP-1 injectable drug products, bacteriostatic water, and injectable peptides from an unlicensed source, identified as Heal Well. NOTE: Heal Well is an entity that is not a licensed wholesale drug distributor, outsourcing facility, compounding pharmacy, or drug manufacturer in the United States and does not have Food and Drug Administration (FDA) manufacturer registration.

        i. During the inspection, the clinic possessed the following dangerous drugs obtained from Heal Well:

            1. Eighteen (18) vials purporting to be GLP-1 GIP, 60mg, and one (1) vial purporting to be GLP-1 GIP 25mg.

                a. The vials all contained white powder, were labeled as sterile multidose vials "For Clinical Use Only", did not contain the name of the manufacturer, and contained a statement noting to "refrigerate once reconstituted." NOTE: The FDA does not have a definition for the phrase "for clinical use only", and the identity, quality, and integrity of the drugs could not be determined.

                b. Purchase records indicate that the clinic purchased approximately 37 to 45 total vials of purported GLP-1s from Heal Well between on or about July 16, 2025, to on or about October 8, 2025.

            2. One (1) vial containing white powder, purported BPC-157, 10mg, labeled as a sterile multidose vial and "Research Use." NOTE: BPC-157 injectable is not FDA-approved. Research Use Only drugs are not FDA-approved; they are drugs specifically

designed and labeled for use in scientific research and not for clinical or diagnostic purposes

a. The vial did not contain the name of the manufacturer, was not labeled with beyond use date, and did not have reconstitution instructions.

b. The product was in a plastic container designed to hold multiple vials. Owner Wade Banker denied purchasing additional vials or administering the peptides to patients.

c. Purchase records obtained following the inspection, shows the clinic purchased five (5) vials of BPC-157 10mg for $120 each for a total of $600.

3. Ten (10) vials purported bacteriostatic water, labeled as 10ml multiple dose vials, not for resale and for "clinical use only". The vial label also stated 0.9% benzyl alcohol was added and the product for not for use in neonates. The product stated it was for drug diluent use only and was labeled as RxOnly, but no storage information or manufacturer/distributor information was listed on the vial label.

ii. Clinic staff was initially unable to provide any information regarding Heal Well, including address, telephone number, Board license number, or any sales invoices for drugs purchased through it. Following the Board's inspection, on 10/24/25, clinic owner Banker provided follow-up information regarding Heal Well Corp:

1. Banker stated that he had relied on Heal Well's representation that it was an FDA-approved supplier of GLP-1s and peptides but had not independently verified.

2. Banker acknowledged information on the Heal Well website, which stated their medications "may be considered investigational, experimental, or for clinical research only, and may not be FDA-approved", but denied that those disclaimers were present during his account creation with the company.

3. Banker stated Heal Well company representative Tyler Papa stopped responding to his communications, supplied unverifiable business information and failed to identify a legitimate manufacturer for the products supplied by Heal Well to Luxe Laser.

4. Luxe Laser/Banker apologized for the illegal purchases made through Heal Well and committed to significant internal changes to prevent similar incidents from occurring in the future, noting the bad-faith misrepresentation by Heal Well.

b. The clinic possessed adulterated dangerous drugs purchased from an unlicensed source and did not conduct a wholesaler query for an Ohio Board of Pharmacy license prior to purchasing dangerous drugs at wholesale, or annually, as required. See Allegation #2a. The failure to query the license roster prior to purchasing was a repeat violation from a Board inspection conducted in 2023.

c. The clinic compounded syringes of GLP-1 GIP and vitamin B-12.

   i. Syringes of GLP-1 GIP were compounded and the contents of vial drawn into unit of use syringes in ambient air and personally furnished to patients for use.

      1. The syringes of GLP-1 GIP were labeled as tirzepatide and were not assigned a beyond use date. A one-month supply was personally furnished to patients at a time, exceeding the 6-hour beyond use date required for immediate use compounding.

   ii. The clinic compounded syringes of vitamin B-12 by drawing the contents from a bulk sterile vial into unit of use syringes in ambient air for office use in advance of patient need.

      1. Syringes were not labeled and were stored in a box at the bottom of the refrigerator.

      2. Staff stated the quantity of prefilled syringes in the refrigerator was about a 1-month supply, which exceeded the 6-hour beyond use date required for immediate use compounding.

   iii. The clinic did not have compounding procedures or training and failed to maintain compounding records.

d. The clinic documented the administration and personally furnishing of GLP-1-GIP as tirzepatide, however no clinical information was available confirm the vials labeled GLP-1-GIP were tirzepatide. Certificates of analysis for semaglutide and tirzepatide product did not match the lot numbers on the GLP-1-GIP drug vials on hand.

e. The clinic failed to maintain records of receipt for drugs purchased. This was a repeat violation from a Board inspection conducted in 2023.

f. The clinic created administration records which did not contain the name of the drug. Administration records stated tirzepatide was administered or personally furnished when the drug product administered was GLP-1 GIP. Information was not provided showing the two drugs were the same.

g. The clinic issued inappropriate standing orders for the administration of Botox.

   i. APRN Bakhsh stated she conducted an annual assessment for patients and then issued an order for Botox which permitted the administering RN to determine the dose, location of administration and frequency of administration based on the RN/Patient consultation and/or RN clinical judgement.

   ii. Orders were signed by the APRN using a stamp.

iii. The APRN order failed to contain a patient specific dosage or dosage range based on objective measures.

h. Patient-specific prescriptions were used as office stock.

i. Patient-specific non-sterile compounded benzocaine/lidocaine/tetracaine dispensed by Board-licensed entities, AnazaoHealth and Accudose Pharmacy, were observed stored in the clinic drug stock. The prescriptions were issued to clinic owner Wade Banker but were used as office stock.

i. Drug storage and handling.

i. The clinic stored Botox® in the freezer. Botox is labeled for storage between 2-8°C for up to 36 months. The freezer temperature was observed at -15°C.

1. There was no record of temperature monitoring in the freezer used for drug storage although a temperature monitoring device was present.

ii. The clinic stored other medications, including pre-drawn syringes of Vitamin B-12, reconstituted GLP-1 GIP, NAD+ and Liraglutide, in a refrigerator in the nursing office.

1. There were no temperature monitoring devices or temperature monitoring logs for this refrigerator.

2. A beverage can was observed stored in this refrigerator with the medications.

iii. The clinic did not maintain temperature logs with minimum daily observations or utilize a temperature monitoring system capable of detecting and alerting staff to temperature excursions.

iv. The clinic had no policies or procedures in place to respond to out of range temperature readings.

v. The clinic's failure to monitor the temperature of refrigerated and frozen drug storage areas was a repeat violation from a Board inspection conducted in 2023.

vi. Multi-dose vials were not properly labeled or stored.

1. Multiple open, reconstituted, or punctured multi-dose vials (MDVs) were not dated with a date opened or 28-day beyond use date (BUD).

2. Vials labeled single use were retained in the refrigerator for use on multiple patients. Punctured single-dose vials of Botox were observed opened/used and stored in the injectable treatment room.

3. MDVs were found with the foil seal removed and the vial septum not secured to the sterile vial, compromising the sterility of the vial contents, but retained for use on multiple patients.

j. Adulterated drugs were comingled in the active drug stock.

i. A significant quantity of expired drugs was found throughout the active drug stock storage areas. This was a repeat violation from Board inspections conducted in 2018 and 2023.

ii. A full, uncapped (sterile needle exposed) syringe containing a cosmetic filler was observed in the treatment room drawer housing fillers for administration.

iii. All, or nearly all, drug stock in the clinic crash cart was expired, with the oldest expired product dated 3/2023. The crash cart had not been checked since 4/2024.

iv. A product expiring 2/2019 was found in other drug stock areas.

v. A pre-filled syringe in a treatment room labeled as epinephrine was dated 10/19/2025, but the time drawn up was not recorded and the clinic's stock of epinephrine had expired 9/30/2025. If the drug used to prefill the syringe had not been expired, it was required to be used within 6 hours of being drawn into the syringe.

vi. Two of the patient specific containers of benzocaine/lidocaine/tetracaine used as clinic stock were expired.

vii. One vial of Liraglutide from Olympia Pharmacy did not contain a lot number or expiration date from the manufacturer.

viii. The clinic failed to maintain records of drug disposal from inventory. This was a repeat violation from Board inspections conducted in 2018 and 2023.

ix. Records of annual controlled substance inventories could not be produced during the inspection or after. This was a repeat violation from Board inspections conducted in 2018 and 2023.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.52(A) of the ORC, Prohibited acts, each, a misdemeanor of the fourth degree, each punishable by a maximum penalty of $2,000 if committed by an organization: The following acts and causing them are prohibited:

a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated[1] or misbranded,[2] ORC Section 3715.52(A)(1); and/or

b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and/or

c. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, ORC Section 3715.52(A)(3).

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(F) of the ORC, effective April 9, 2025, Selling, purchasing, distributing, or delivering dangerous or investigational drugs – No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, punishable by a maximum penalty of $5,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(B) of the ORC, Verification of license prior to transactions – Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the roster established pursuant to section 4729.59 of the Revised Code to confirm the seller is licensed to engage in the sale or distribution of dangerous drugs at wholesale, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019, Verification of licensure prior to sale or purchase, each violation punishable by a maximum penalty of $1,000:

   a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to confirm any of the following:

      i. The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or

      ii. The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2); and/or

[1] ORC Section 3715.63 – When drug or device is adulterated.
[2] ORC Section 3715.64 – Misbranded drug or device.

b. If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code, OAC Rule 4729:5-3-04(B).

5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-3-06 of the OAC, as effective March 1, 2019, Storage of adulterated drugs, each violation punishable by a maximum penalty of $1,000:

   a. To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration, OAC 4729:5-3-06; and/or

      i. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons, OAC 4729:5-3-06(A); and/or

      ii. Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in agency 4729 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons, OAC Rule 4729:5-3-06(B).

6. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-03 of the OAC, as effective February 4, 2021, Security, control and storage of dangerous drugs, each violation punishable by a maximum penalty of $1,000:

   a. The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-03(A); and/or

   b. During non-business hours, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, non-controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs, OAC Rule 4729:5-19-03(I); and/or

   c. All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

i. Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

1. Temperature logs with, at a minimum, daily observations, OAC Rule 4729:5-19-03(K)(1)(a); or

2. A temperature monitoring system capable of detecting and alerting staff of a temperature excursion, OAC Rule 4729:5-19-03(K)(1)(b); and/or

ii. The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs, OAC Rule 4729:5-19- 03(K)(2); and/or

iii. The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs, OAC Rule 4729:5-19-03(K)(3); and/or

d. Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated, OAC Rule 4729:5-19-03(L); and/or

e. Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(M).

7. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020, General security requirements, each violation punishable by a maximum penalty of $1,000:

a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

8. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, Record Keeping, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000:

a. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred, OAC Rule 4729:5-19-04(A); and/or

b. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the

recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement, OAC Rule 4729:5-19-04(B); and/or

c. Records of temperature control monitoring described in paragraph (K)(1) of rule 4729:5-19-03 of the Administrative Code shall include any of the following:

   i. For temperature logs, either:

      1. The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(a); and/or

      2. For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(b); and/or

   ii. For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion, OAC Rule 4729:5-19-04(C)(2); and/or

d. Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drugs were personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver, OAC Rule 4729:5-19-04(D); and/or

e. Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration and for non-controlled substance dangerous drugs: the identification of the health care professional administering the drug. * * *, OAC Rule 4729:5-19-04(E)(1)(a); and/or

f. Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph, OAC Rule 4729:5-19-04(E)(2); and/or

g. Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification, OAC Rule 4729:5-19-04(E)(3); and/or

h. Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:5-19-04(F); and/or

i. All records maintained in accordance with this rule and rule 4729:5-19-03 of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years, OAC Rule 4729:5-19-04(J).

9. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-3-07 of the OAC, as effective March 1, 2019, Controlled substance inventory requirements, each violation punishable by a maximum penalty of $1,000:

a. All controlled substance inventories performed in accordance with this rule shall be conducted on an annual basis. The annual inventory may be taken on any date which is within thirteen months of the previous inventory date, OAC Rule 4729:5-3-07(B); and/or

b. The terminal distributor's responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC Rule 4729:5-3-07(C); and/or

c. All inventory records shall be maintained for a period of three years from the completion date of the inventory and made readily retrievable, OAC Rule 4729:5-3-07(D).

10. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:5-3-12 of the OAC, as effective March 1, 2020, Protocols for medication administration, each violation punishable by a maximum penalty of $1,000:

a. A terminal distributor of dangerous drugs may distribute or dispense dangerous drugs for administration pursuant to a pre-printed order. As used in this rule, "pre-printed order" means a patient specific and dose specific order for the administration of a specific drug or drugs prescribed by a licensed health care professional authorized to prescribe drugs. The prescriber must complete an assessment and make a diagnosis prior to initiating a pre-printed order in accordance with the prescriber's scope of practice. The pre-printed order may only be initiated upon the order of a prescriber authorized by law to prescribe the drugs listed in the pre-printed orders. The drugs shall be administered by an individual authorized by law to administer the drugs, OAC Rule 4729:5-3-12(C); and/or

b. A pre-printed order described in paragraph (C) of this rule shall:

i. Include the name of the patient; drug name and strength; specific instructions of how to administer the drug, dosage, and frequency; instructions of any patient specified dosage range based on objective measures such as calculations and patient physiologic data; signature of the prescriber or some other form of positive identification of the prescriber as defined in agency 4729 of the Administrative Code; and date of signature, OAC Rule 4729:5-3-12(D)(1); and/or;

ii. Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects, OAC Rule 4729:5-3-12(D)(2); and/or

iii. Can be performed without requiring the exercise of medical judgment, OAC Rule 4729:5-3-12(D)(3); and/or

iv. Will lead to results that are reasonably predictable and safe, OAC Rule 4729:5-3-12(D)(4); and/or

v. Can be performed safely by the individual authorized to administer the drugs and without the need for repeated medical assessments, OAC Rule 4729:5-3-12(D)(5); and/or

vi. Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of initiation. A pre-printed order which becomes a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph, OAC Rule 4729:5-3-12(D)(6); and/or

vii. Be made readily retrievable, OAC Rule 4729:5-3-12(D)(7); and/or

viii. If performed improperly, would not present a danger of immediate and serious harm to the patient, OAC Rule 4729:5-3-12(D)(8); and/or

ix. Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care, OAC Rule 4729:5-3-12(D)(9).

11. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021, Non-Hazardous Drugs Compounded by a Prescriber, each violation punishable by a maximum penalty of $1,000:

    a. Except as provided in paragraph (C) of this rule, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(B); and/or

    b. For all immediate-use, non-hazardous sterile compounded drug preparations, a prescriber shall comply with either:

        i. Rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-03(C)(1); or

        ii. United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(C)(2); and/or

    c. The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for all of the following:

i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-03(E)(1); and/or

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-03(E)(2); and/or

iii. Compliance with Title 21 U.S. Code section 353a (November 27, 2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-03(E)(3); and/or

iv. Ensuring documented training and competency of compounding personnel, OAC Rule 4729:7-3-03(E)(4); and/or

v. Ensuring environmental control of the compounding areas, OAC Rule 4729:7-3-03(E)(5); and/or

vi. Ensuring compounded drug preparations maintain quality and sterility until administered or personally furnished, OAC Rule 4729:7-3-03(E)(6); and/or

vii. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-03(E)(7); and/or

viii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-03(E)(8); and/or

ix. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-03(E)(9).

12. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021, Immediate-use, sterile non-hazardous drugs compounded by a prescriber, each violation punishable by a maximum penalty of $1,000:

    a. The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all the following:

        i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-04(A)(1); and/or

        ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-04(A)(2); and/or

        iii. Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-04(A)(3); and/or

        iv. Ensuring that compounded drug preparations maintain quality and sterility until administered, OAC Rule 4729:7-3-04(A)(5); and/or

v. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(A)(6); and/or

b. Immediate-use, sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-03 of the Administrative Code if all the following criteria are met:

i. The beyond-use date for an immediate-use compounded drug preparation is as follows:

1. Except as provided in paragraph (B)(4)(b) of this rule, no later than six-hours following preparation of the drug, OAC Rule 4729:7-3-04(B)(4)(a); and/or

ii. Unless administered immediately, the compounded drug preparation shall bear a label listing all the following:

1. Except for preparations compounded in accordance with paragraph (G)(2) of this rule, patient identification information, including the patient's first and last name, OAC Rule 4729:7-3-04(B)(6)(a); and/or

2. The name and quantity of each ingredient, OAC Rule 4729:7-3-04(B)(6)(b); and/or

3. The beyond-use date and time prepared, OAC Rule 4729:7-3-04(B)(6)(c); and/or

4. The name or initials of the person who prepared the compounded drug preparation, OAC Rule 4729:7-3-04(B)(6)(d); and/or

iii. Immediate-use compounded drug preparations are for administration only and shall not be personally furnished by a prescriber, OAC Rule 4729:7-3-04(B)(7); and/or

c. Unless administered within one-hour of preparation, sterile compounded drug preparations for immediate-use shall be prepared in a designated clean medication area that is not adjacent to areas where potentially contaminated or hazardous items are placed. Such an area shall be limited to compounding personnel and shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Cleaning and disinfection agents must be selected and used with careful consideration of compatibility, effectiveness, and inappropriate or toxic residues. Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile seventy per cent isopropyl alcohol, which is allowed to dry before compounding begins, OAC Rule 4729:7-3-04(C); and/or

d. Preparations that are deemed category two, medium-risk level, or high-risk level compounded drug preparations as defined in United States pharmacopeia chapter <797> shall not be prepared as immediate-use, OAC Rule 4729:7-3-04(D); and/or

e. Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code, OAC Rule 4729:7-3-04(E); and/or

f. Records of drug compounding shall be maintained pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(H); and/or

g. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

    i. Inspect and approve the compounding process, OAC Rule 4729:7-3-04(L)(1); and/or

    ii. Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-04(L)(2); and/or

h. The requirements of paragraph (M)(2) of this rule do not apply to either of the following:

    i. A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(1); or

    ii. A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(2); and/or

i. All the following are required to administer a compounded drug preparation in accordance with paragraphs (M)(1) and (M)(2) of this rule:

    i. Verify the accuracy of:

        1. Drug name, OAC Rule 4729:7-3-04(N)(3)(a); and

        2. Drug strength and dosage form, OAC Rule 4729:7-3-04(N)(3)(b); and

        3. Drug volume, OAC Rule 4729:7-3-04(N)(3)(c); and

        4. Rate of administration, OAC Rule 4729:7-3-04(N)(3)(d); and

        5. Route of administration, OAC Rule 4729:7-3-04(N)(3)(e); and

        6. Expiration dates/times, OAC Rule 4729:7-3-04(N)(3)(f); and

        7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-04(N)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-04(N)(4).

13. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-06 of the OAC, as effective March 31, 2021, Record Keeping, each violation punishable by a maximum penalty of $1,000:

    a. The responsible person shall maintain the following records relating to the compounding of dangerous drugs:

        i. All drug orders and records, including logs, relating to the compounding of drugs. Such drug orders and records may be retained by any process providing an exact duplicate of the original order or prescription, OAC Rule 4729:7-3-06(A)(1); and/or

        ii. Records of each drug compounded shall, at a minimum, include all the following:

            1. The full name of the patient, unless compounded in accordance with paragraph (G)(2) of rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-06(A)(3)(a); and/or

            2. Name, strength, and dosage form of the compounded drug, OAC Rule 4729:7-3-06(A)(3)(b); and/or

            3. Name and quantity of each ingredient, OAC Rule 4729:7-3-06(A)(3)(c); and/or

            4. If a controlled substance, the disposition of unused drug(s) and amount, OAC Rule 4729:7-3-06(A)(3)(d); and/or

            5. Date and time of preparation, OAC Rule 4729:7-3-06(A)(3)(e); and/or

            6. Beyond-use date of the compounded drug, OAC Rule 4729:7-3-06(A)(3)(f); and/or

            7. The positive identification of the personnel responsible for compounding the drug, OAC Rule 4729:7-3-06(A)(3)(g); and/or

            8. The positive identification of either of the following:

                a. Person or persons performing medication validation prior to the compounded drug being administered, OAC Rule 4729:7-3-06(A)(3)(h)(i); and/or

                b. The prescriber personally furnishing the compounded drug, OAC Rule 4729:7-3-06(A)(3)(h)(ii).

14. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible person – terminal distributor, as effective April 25, 2022, each punishable by a maximum penalty of $1,000:

    a. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC Rule 4729:5-2-01(E)(4); and/or

    b. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(E)(6).

15. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective October 3, 2023, TDDD license requirements, each violation punishable by a maximum penalty of $1,000:

    a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or

    b. A… licensed health professional authorized to prescribe drugs… will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or

    c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C).

16. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective April 4, 2023, each violation punishable by a maximum penalty of $1,000:

    a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or

    b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or

    c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or
    d. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or

e. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).

17. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of $1,000:

    a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or

    b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or

    c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, OAC Rule 4729:5-4-01(B)(4); and/or

    d. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor, OAC Rule 4729:5-4-01(B)(6); and/or

    e. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and/or

    f. Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice, OAC Rule 4729:5-4-01(B)(18); and/or

    g. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:5-4-01(B)(23).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the Ohio Board of Pharmacy, if you request such a hearing within thirty (30) days of the date of the service of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the service of this notice, the Ohio Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE OHIO BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/zas/rlj

cc: David Geiger, Ohio Board of Nursing, at: david.geiger@nursing.ohio.gov