



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

IN THE MATTER OF:

CASE NO. A-2026-0324

I Beauty MedSpa PLLC

c/o Dr. Fadi Ibrahim
7640 Sylvania Ave
Suite H
Sylvania, OH 43560

License No. 02-62001785

September 15, 2026

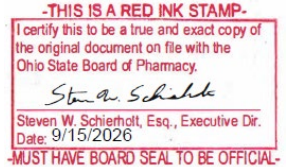
Dear I Beauty MedSpa PLLC and Dr. Fadi Ibrahim:

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS I Beauty MedSpa PLLC'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 I Beauty MedSpa PLLC's method used to possess or distribute dangerous drugs. As such, the Board summarily suspends I Beauty MedSpa PLLC's license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code (ORC) 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 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. I Beauty MedSpa PLLC ("I Beauty"), located at 7640 Sylvania Ave, Suite H, Sylvania, Ohio, is a licensed TDDD under license number 02-62001785 and lists owner Dr. Fadi Ibrahim [Ohio Medical Board license no. 35.150055] as the Responsible Person.

ALLEGATIONS

1. On or about September 10, 2026, Board staff conducted an inspection at I Beauty Medspa, located at 7640 Sylvania Ave, Suite H, Sylvania, Ohio. During the inspection, office support staff Katie Badenhop and esthetician Megham Quinlin were present; no licensed medical practitioners, including Responsible Person (RP) Dr. Fadi Ibrahim, were on site.
 - a. In the active drug stock, Board staff located the following illegal and unapproved dangerous drugs intended for injection:
 - i. Two (2) vials of purported Tesamorelin 10mg, in white powder form (Alpha BioMed)
 1. NOTE: Alpha Biomed 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. Dangerous Drugs purchased from Alpha BioMed are misbranded and adulterated.
 - ii. Four (4) vials of 4X Blend 5mg/5mg/500mcg/2.5mg (mixture of purported GHRP-2/ Tesamorelin MGF/ Ipamorelin) in white powder form (Alpha BioMed);
 - iii. One (1) vial of Glow 70 50/10/10mg (mixture of purported GHK-Cu, BPC-157, and TB-500), in white powder form (Alpha BioMed);
 - iv. One (1) vial of Glow 50 30/10/10mg, (mixture of purported GHK-Cu, BPC-157, and TB-500), in white powder form (Alpha BioMed);
 - v. One (1) vial of purported Dual Regulator DIA-39-C20 120mg, in white powder form (no manufacturer information on label)
 1. NOTE: Drugs not labeled with any manufacturer information are misbranded and adulterated.
 - vi. Seven (7) vials of purported Triple Regulator TIA-39-C20 60mg, in white powder form (no manufacturer information on label);

- vii. Two (2) vials of purported Slim 50mg, in white powder form (no manufacturer information on label);
 - viii. Two (2) vials of Liporase
 - 1. NOTE: Labeling and manufacturer indicate the product is of South Korean origin. Liporase is not an FDA-approved product.
 - ix. One (1) vial of purported Trim 120mg, in white powder form (no manufacturer information on label);
 - x. One (1) Vial of Klow 80 50/10/10/10mg (a mixture of purported GHK-CU / KPV / BPC-157 / TB-500) in white powder form (Alpha BioMed);
 - xi. Two (2) vials of purported Epithalon 50mg, in white powder form (Alpha BioMed);
 - xii. Six (6) vials of 3X Blend 5/5/2.5mg (mixture of purported Tesamorelin, Mechano Growth Factor / MGF, and Ipamorelin), in white powder form (Alpha BioMed);
 - xiii. Three (3) vials of 2X Blend 5/5mg (mixture of purported CJC-1295 (without DAC) and Ipamorelin), in white powder form (Alpha BioMed);
 - xiv. Three (3) vials of purported NAD + 1000mg, in white powder form (Alpha BioMed);
 - xv. One (1) vial of purported IGF-1 LR3 1mg, “reconstituted” in liquid form (Alpha BioMed).
- b. In the clinic’s drug storage refrigerator with the active drug stock was a small clear pouch marked “Dr. I” was located, containing six vials of different unapproved peptide products.
- c. Board staff spoke with RP Dr. Ibrahim via telephone.
- i. When asked about the unapproved drugs located, Dr. Ibrahim stated he knew the products were unapproved but claimed because he was a medical doctor, he could use the products “off label.”
 - ii. Dr. Ibrahim stated he prescribes GLP-1 products as patient specific, has the drugs delivered to his office, and administers injections to patients at the office.
 - iii. Regarding other peptide dangerous drugs, Dr. Ibrahim stated he “reconstitutes” the product in his office and the patient takes it home with hypodermic syringes to self-administer.
 - iv. Dr. Ibrahim confirmed the clear pouch in the refrigerator (see Allegation (1)(c)) contained injectable peptides for his personal use.

- d. Warnings and warnings requiring written responses were issued for violations including the following:
- i. Clinic purchased drugs from unlicensed wholesale distributors. Board Inspectors observed vials for products where manufacturer information or distributor information was missing or in foreign language.
 - ii. Clinic did not conduct a wholesaler query prior to drug purchases or annually as required. *Note: this was a repeat violation from a Board inspection on 11/20/2025.*
 - iii. Expired and adulterated drugs in the active drug stock.
 - 1. Research Use Only products and foreign language products, including foreign language liporase, were present within the active drug stock.
 - 2. A large amount of punctured multi-dose drug vials were not properly marked with date of first puncture or beyond use date. *Note: this was a repeat violation from a Board inspection on 11/20/2025.*
 - 3. A large amount of single dose drug vials with evidence of puncture were still in the active drug stock.
 - 4. The clinic had pre-filling syringes that were well beyond the 6-hour beyond use date. They were also unmarked.
 - 5. Observed some vials where the manufacturer metal crimping had been removed allowing staff access to contents of vial via removal of sterile rubber septum. Vials were considered adulterated.
 - 6. A large amount of expired drugs were located within active drug stock (oldest expiration 6/2023) including expired Narcan (expired 4/2025). *Note: this was a repeat violation from a Board inspection on 11/20/2025.*
 - 7. Observed filled syringes in a baggie labeled with patient name and drug name "Semaglutide."
 - a. Syringes were not individually labeled when repackaged and do not appear to be applying a label bearing requirements of the rule.
 - b. Clinic did not have a log of when syringes were drawn up but admitted they were not drawn up that day. The syringes were not labeled with a 6 hour beyond use date and are not appropriate for personally furnishing.
 - 8. Observed a drawn-up syringe of a red liquid in clinic fridge. Syringe was not labeled.

9. Observed a vial of Sodium Bicarbonate labeled "For Intravenous Use Only" and "Single Dose Vial."
 - a. Sodium Bicarbonate had multiple punctures in rubber septum and stored within active drug stock indicating multi-dose use.
 - b. Clinic staff could not produce compounding records for use of Sodium Bicarbonate.
- iv. Clinic is repackaging compounded drugs and personally furnishing to patients.
 1. Observed several glass containers and amber vials containing cream or ointment. Clinic staff state some of the containers are over the counter balms (e.g. petroelum jelly) and compounded ointments (such as Benzocaine/Lidocaine/Tetracaine, HQ 4%).
 - a. Containers and vials are repackaged from larger compounding containers by clinic staff for patients to administer at home.
 - b. Vials/Containers did not have a label and clinic staff could not identify contents of some of these substances.
 2. Observed compounded Benzocaine/Lidocaine/Tetracaine 20%-10%-10% ointment dispensed patient specific in Dr. Fadi Ibrahim's name. Ointment was being used as clinic drug stock and was being repackaged into smaller vials and personally furnished to patients.
- v. Drug stock storage refrigerators and freezer did not have any temperature monitoring in place.
- vi. The main drug refrigerator was very dirty, and drugs were sticking to the bottom.
 1. Refrigerators had condensation and medication boxes stored within were soggy.
 2. Observed a vial of compounded Ascorbic Acid where contents had spilled out and encrusted top of vial and other sterile vials stored in area.
 3. Some vials found in fridge were "sticky" or coated in a sticky-like substance.
 4. Freezer had considerable ice buildup around door and inside of unit.
- vii. Dangerous drugs and hypodermic syringes are stored in unlocked cabinets and open shelves.
 1. Landlord/leasing office staff and cleaning/janitorial staff both have keys to the clinic's suite and would be able to access to hypodermic syringes and dangerous drugs when staff are not on site to supervise.

- viii. Clinic does not maintain records of receipt for drug purchases at this location. Clinic states some invoices may be stored at an offsite location in Michigan.
- ix. Clinic was acting as an alternate location for delivery of patient-specific compounded drugs, when it did not meet the requirements to have the drugs delivered to an alternate location. Board staff located several amber vials for Semaglutide 5mg/mL labeled with patient names compounded by Restorative Compounding Pharmacy & Wellness. This medication was found to expired (4/18/2026) and was segregated for disposal during inspection. *Note: this was a repeat violation from a Board inspection on 11/20/2025.*

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.52 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 adulterated¹ 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); and/or
 - d. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code, ORC Section 3715.52(A)(4).
2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, 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, each violation is a misdemeanor of the first degree, each violation 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, constitutes a violation of Section 4729.60(B) of the ORC, 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

¹ ORC Section 3715.63: When a drug or device is adulterated

² ORC Section 3715.64: Misbranded drug or device

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, constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019, 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
 - 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 July 1, 2024, 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 4729:5-3-14(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).
7. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-02 of the OAC, Personally furnishing dangerous drugs, as effective April 1, 2026, each violation punishable by a maximum penalty of \$1,000:
- a. A prescriber who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, shall affix to the container a label showing:
 - i. The name and address of the prescriber, OAC Rule 4729:5-19-02(A)(1); and/or
 - ii. The name of the patient for whom the drug is intended, OAC Rule 4729:5-19-02(A)(2); and/or
 - iii. Name and strength of the drug, OAC Rule 4729:5-19-02(A)(3); and/or
 - iv. Directions for use, OAC Rule 4729:5-19-02(A)(4); and/or
 - v. Date furnished, OAC Rule 4729:5-19-02(A)(5); and/or
 - vi. If a compounded drug, the statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label, OAC Rule 4729:5-19-02(A)(6).
8. 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, Security, control and storage of dangerous drugs, as effective April 1, 2026, 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, hypodermics 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, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections, OAC Rule 4729:5-19-03(H); and/or
 - c. 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

- d. All records relating to the receipt, administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access, OAC Rule 4729:5-19-03(J); and/or
 - e. 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
 - f. 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
 - g. 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).
9. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, Record keeping, as effective April 1, 2026, 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 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
 - e. 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).
10. 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); and/or
 - d. A prescriber shall not compound drug preparations unless a specific patient need exists. Compounding for anticipated needs or engaging in compounding practices where multiple non-patient specific doses are produced in a single activity is prohibited, OAC Rule 4729:7-3-03(J).
11. 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).
12. 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).

13. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-24 of the OAC, Dispensing dangerous drugs to an alternate location, as effective August 9, 2026, each violation punishable by a maximum penalty of \$1,000:
 - a. A terminal distributor of dangerous drugs that serves as an alternate location shall comply with the following:
 - i. Except for terminal distributors of dangerous drugs who are pharmacies, only receive drugs from the dispensing pharmacy if there is clear and convincing evidence that the delivery of a dangerous drug directly to the patient would result in:
 1. Danger or harm to public health or safety, OAC Rule 4729:5-3-24(D)(3)(a); or
 2. Danger or harm to the patient without increased involvement by a health care professional in the patient's drug therapy, OAC Rule 4729:5-3-24(D)(3)(b); and/or
 - b. The state board of pharmacy may restrict a site from acting as an alternate location if it has clear and convincing evidence that the activities of that location present the following:
 - i. Danger or harm to public health or safety, OAC Rule 4729:5-3-24(E)(1); or; or
 - ii. Danger or harm to the patient, OAC Rule 4729:5-3-24(E)(2).
14. Such conduct as set forth in the Allegations Section, if proven, 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 violation 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729.57(B)(5); 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, ORC Section 4729.57(B)(7); and/or
 - f. 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); 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/jrn

cc: Ohio Medical Board, Judith.Rodriguez@med.ohio.gov