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Steven W. Schierholt, Esq., Executive Dir.
Date: 1/21/2025
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SUMMARY SUSPENSION/NOTICE OF OPPORTUNITY FOR HEARING
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE

IN THE MATTER OF: **CASE NO. A-2025-0012**

Jiva Med Spa & Plastic Surgery Center **License No. 02-2814450**
c/o Rakesh A. Nanda, MD
4235 Indian Ripple Road
Dayton, Ohio 45440

January 21, 2025

Dear Jiva Med Spa & Plastic Surgery Center and Dr. Rakesh A. Nanda:

You are notified, in accordance with Section 119.07 of the Revised Code, the State of Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Jiva Med Spa & Plastic Surgery Center'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 Jiva Med Spa & Plastic Surgery Center's method used to possess or distribute dangerous drugs, and the method of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor. As such, the Board summarily suspends Jiva Med Spa & Plastic Surgery Center's license as a Terminal Distributor of Dangerous Drugs. Pursuant to Division (D)(1) of Section 4729.57 of the ORC, Jiva Med Spa & Plastic Surgery Center must immediately surrender license number 02-2814450 to the Board.

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. 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. Pursuant to Section 4729.571(A)(2) 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 of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor.

4. Jiva Med Spa & Plastic Surgery Center, located at 4235 Indian Ripple Road, Dayton, Ohio, is a licensed TDDD under license number 02-2814450 and lists Rakesh A. Nanda, MD, [State Medical Board of Ohio license number 35.093863] as the Responsible Person and owner.

ALLEGATIONS

1. On or about January 7, 2025, an inspection at Aesthetic Essentials, TDDD license number 02-72000052, a prescriber clinic licensed by the Board, revealed Aesthetic Essentials had been purchasing "For Research Use Only" drugs from Jiva Med Spa and/or Dr. Nanda. Aesthetic Essentials confirmed Dr. Nanda is a physician and not a drug wholesaler licensed with the Board. Jiva Med Spa is also not a drug wholesaler licensed with the Board. The Responsible Person and owner of Aesthetic Essentials stated when she ordered these drugs, she would pay Jiva Med Spa and/or Dr. Nanda directly through the Zelle app.

    a. A review of purchasing records provided to the Board by Aesthetic Essentials on January 14, 2025, confirmed 14 transactions were made by Aesthetic Essentials to Jiva Med Spa, totaling approximately $37,950.

    b. The research drugs seized from Aesthetic Essentials appeared to Board inspectors be the same "Research Use Only" drugs found at Jiva Med Spa's Dayton and Mason locations.

2. On or about January 8, 2025, a Board Agent and a Board Specialist (Board inspectors) conducted an inspection at Jiva Med Spa & Plastic Surgery Center (Jiva Med Spa (Dayton)), located at 4235 Indian Ripple Road, Dayton, Ohio. The Board inspectors met with Danielle Glascoe and Nicole Walker, PA, during the inspection. Jiva Med Spa (Dayton)'s Responsible Person and owner, Rakesh A. Nanda, MD, was not present at the time of the inspection.

3. The inspection identified Jiva Med Spa (Dayton) was in possession of tirzepatide labeled "For Research Use Only," semaglutide labeled "Research Purposes Only," and retatrutide labeled "For Research Use Only." The vials had no National Drug Code (NDC).

    a. It was confirmed by staff that these drugs were being administered to patients at the clinic. Staff neither confirmed nor denied the clinic was personally furnishing these drugs.

b. The Board inspectors observed vials of retatrutide, semaglutide, and trizepatide reconstituted in a drugs refrigerator. Staff explained the vials were for administration to patients that day. The vials did not have beyond use dates (BUD).

c. The Board inspectors also found drug vials labeled with instructions to store refrigerated at 2 degrees Celsius to 8 degrees Celsius that were stored in an unrefrigerated file cabinet. Staff stated they believed the drugs only needed to be refrigerated after reconstitution took place.

i. Note: Research Use Only drugs are not approved by the Food and Drug Administration. They are drugs specifically designed and labeled for use in scientific research and not for clinical or diagnostic purposes.

ii. Note: Retatrutide is not a Food and Drug Administration-approved medication. During the time of use at Jiva Med Spa (Dayton), it was undergoing Phase III trials. Jive Med Spa (Dayton) was not part of these trials.

4. The Board inspectors questioned Jiva Med Spa (Dayton) staff about the "For Research Use Only" drugs. Staff stated they did not know where the research drugs came from; Dr. Nanda purchases the drugs and delivers them to the clinic on Tuesdays. Staff believed the drugs were shipped to the Columbus office and brought to this location. Ms. Walker indicted she started working at the clinic in November 2024 and she noticed the "research" labeling and questioned the products.

a. Ms. Walker stated the manager at Jiva Med Spa Columbus, Kyla Evans, explained the patient consent forms- that patients sign before an injection- notified patients of the research use of the drugs, which allowed the clinic to administer the research use drugs. Neither Ms. Glascoe nor Ms. Walker was aware of a clinical trial being conducted at the clinic.

5. During the inspection, Jiva Med Spa (Dayton) staff were advised by the Board inspectors they must immediately cease using the research use only drugs. Clinic staff were also advised the "Research Purposes Only" and "For Research Use Only" drugs would be removed from the clinic by the Board inspectors. It was explained that the clinic must only purchase drugs from Ohio Board of Pharmacy licensed drug distributors. The following research only drugs were removed from the clinic:

a. 11 retatrutide vials
b. 23 semaglutide vials
c. 15 tirzepatide vials

6. The inspection conducted on January 8, 2025 resulted in 12 warnings requiring written responses and multiple warnings, including:

a. The clinic is administering retatrutide, tirzepatide and semaglutide labeled "For Research Use Only." The vials are not labeled with a manufacturer. The clinic must only purchase dangerous drugs from Ohio Board of Pharmacy licensed drug distributors.

b. Observed multiple expired drug products, including one (lidocaine injection) dating back to December 2021. Also observed expired fillers. Expired drugs must not be stored for longer than one year.

    i. Adulterated drugs are not stored in a secure area separate from active drug stock.

c. Observed bulk bottles of progesterone compounded capsules. Staff on-site were unsure if these are personally furnished. Also observed Latisse; staff on-site were not sure if this is personally furnished.

d. Staff who were not licensed health care professionals had access to controlled substances.

e. Observed hypodermics stored in patient care rooms in unlocked cabinet drawers. Staff stated two rooms never have unattended patients, but a third room has patients sitting for cryotherapy for 45 minutes to 8 hours at a time and are largely unattended.

f. Observed non-controlled substances stored in a cabinet in the clinic's waiting room, patient care rooms and the storage closet.

    i. Observed progesterone compounded capsules and Latisse in a glass-front cabinet in the waiting room. The cabinet was unlocked during the inspection; staff stated the cabinet is locked at the end of the day.

    ii. The clinic unit in the office building is accessible to the building management team (not licensed health care professionals). There were drop ceilings which were not evaluated for completeness to the deck, and the non-controlled substances were secure from access, during business hours only.

g. Staff stated refrigerator temperature logs are maintained, but they were not provided during the inspection. Observed thermometers in two of the three refrigerators but did not observe a thermometer in the third refrigerator.

h. Observed multi-dose vials onsite. All punctured vials were missing the date opened and the discard date.

i. Observed 3 vials of compounded progesterone capsules. The labels on two bottles stated, "Progesterone 225 mg IR capsule".

i. The third bottle did not state the drug name, strength, lot number, or beyond use date (BUD). The third bottle stated "Compounded by RB. This prescription has been processed and compounded by Carie Boyd Pharmaceuticals of Denton" and included the DEA number and FDA adverse event reporting information, only.

j. Staff was unsure where the records of drug receipt, other than those from Anazao Health, are stored.

k. The clinic did not have a record of non-controlled dangerous drug disposal.

l. The clinic did not have a record of controlled substance disposal.

m. Records of Botox history observed were missing required information.

n. Observed pre-drawn syringes of clear liquid and pre-drawn syringes of reddish liquid in the refrigerators. These syringes were not labeled. Staff stated the clear syringes contained lidocaine and the reddish syringes contained Lipo-Mino. These syringes did not have a BUD. (These syringes must be used within 6 hours and if not used immediately they must be labeled.)

7. An investigation by the Board revealed the “For Research Use Only” drugs were being ordered by Jiva Med Spa and/or Dr. Rakesh Nanda from an entity not licensed in Ohio. This entity is not a legitimate drug wholesale location and not allowed to ship drugs into Ohio. The entity that sold the drugs included a warning on their website that the research drugs are intended as a research chemical only and they are for use in vitro testing and laboratory experimentation only. Additionally, the website’s warning included a statement that, “Bodily introduction of any kind into humans or animals is strictly forbidden by law.”

8. On or about January 9, 2025, a Board Specialist made an additional records request to Jiva Medical Spa (Columbus). On or about January 13, 2025, records were provided to the Board; however, it was explained to the Agent of the Board by Kyla Evans, manager of Jiva Med Spa (Columbus), that a chain of custody is documented when the drugs are delivered to the (Columbus) clinic; however, those records are destroyed afterwards.

9. On or about January 8, 2025, Board inspectors conducted an interview with Dr. Nanda, Responsible Person and owner of three Jiva Med Spa locations, during an inspection at Jiva Med Spa (Columbus). He stated the following:

a. He purchases and administers to patients weight loss injectables including semaglutide and tirzepatide that are labeled “For Research Use Only.”

b. He was conducting his own research as a physician, including obtaining “patient consents” for the use of the research use only drugs.

c. He purchased the research use only drugs from an out-of state unlicensed seller.

d. Dr. Nanda stated he does not use the research use only drugs at his Columbus location due to the clinic being too busy. He only uses the research use only drugs at his Cincinnati and Dayton locations. He further explained the drugs are delivered to the Columbus location and he will personally drive the drugs to the Cincinnati and Dayton locations.

e. He believed his research found the research use only drugs to be superior to the pharmacy compounded semaglutide and tirzepatide he also uses.

f. When asked if he distributes any research use only drugs to other clinics, he stated he did not.

g. He does help other clinics obtain the drugs from the unlicensed seller by either providing the seller's information, or by making the purchase himself on the buying clinic's behalf.

    i. He explained he has collected payment from other clinics and in turn paid the unlicensed seller.

    ii. Dr. Nanda stated he is awarded a reduced purchasing price from the unlicensed seller for aiding their business.

h. He meets owners of other clinics through conferences he attends. He presents at these conferences on the use of the research use only drugs from the unlicensed seller.

i. It was determined by the Board inspectors that the unlicensed seller referenced by Dr. Nanda is not- and has never been- a licensed drug distributor with the Ohio Board of Pharmacy. Board inspectors explained to Dr. Nanda that the purchases were not legal, and he must cease ordering from this entity.

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); and/or

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[1] ORC Section 3715.63 states: A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:
1. It consists, in whole or in part, of any filthy, putrid, or decomposed substance, ORC Section 3715.63(A)(1); and/or
2. It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, ORC Section 3715.63(A)(2); and/or
3. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health, ORC Section 3715.63(A)(3); and/or
4. It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary, ORC Section 3715.63(A)(5); and/or
5. It is not subject to the provisions of division (A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess, ORC Section 3715.63(A)(6).

[2] ORC Section 3715.64 states: A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:
1. Its labeling is false or misleading in any particular, ORC Section 3715.64(A)(1); and/or
2. It is in package form and does not bear a label containing both of the following:
a. In clearly legible form, the name and place of business of the manufacturer, packer, or distributor, ORC Section 3715.64(A)(2)(a); and/or
3. Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, ORC Section 3715.64(A)(5); and/or
4. It is an imitation of another drug, ORC Section 3715.64(A)(10)(b); and/or
5. It is offered for sale under the name of another drug, ORC Section 3715.64(A)(10)(c).

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); and/or

e. The dissemination of any false advertisement, ORC Section 3715.52(A)(5).

2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.68(A) of the ORC, An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 4729.291(A) of the ORC, Drugs personally furnished by prescriber- Except when provided under section 4731.97 of the Revised Code, when a licensed health professional authorized to prescribe drugs personally furnishes drugs to a patient pursuant to division (B) of section 4729.29 of the Revised Code, the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws. Records of purchase and disposition of all drugs personally furnished to patients shall be maintained by the prescriber in accordance with state and federal drug statutes and any rules adopted pursuant to those statutes, 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 Section 4729.51(F) of the ORC, effective October 3, 2023, 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.

5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(A) of the ORC, effective October 3, 2023, No person other than a licensed manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs shall possess for sale, sell, distribute, or deliver, at wholesale, dangerous drugs or investigational drugs or products, each violation is a misdemeanor of the first degree, punishable by a maximum penalty of $5,000 if committed by an organization.

6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(G) of the ORC, effective October 3, 2023, No licensed terminal distributor of dangerous drugs shall engage in the retail sale or other distribution of dangerous drugs or investigational drugs or products or maintain possession, custody, or control of dangerous drugs or investigational drugs or products for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal 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.

7. Such conduct as set forth in the Allegations Section, if proven, each 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 distribution of dangerous drugs at wholesale, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

8. 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, 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).

9. 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, 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).

10. 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. 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

b. 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).

11. 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. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor; ORC Section 4729.57(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, 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).

12. 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).

13. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-24 of the OAC, as effective August 19, 2022, each punishable by a maximum penalty of $1,000:

    a. 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, OAC Rule 4729:5-5-24(A); and/or

    b. Records of dangerous drugs disposed 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 positive identification of the licensed or registered health care professional that performed the disposal, OAC Rule 4729:5-5-24(C); and/or

    c. All records maintained in accordance with this chapter shall be readily retrievable and uniformly maintained for a period of three years, OAC Rule 4729:5-5-24(G).

14. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-09 of the OAC, as effective July 1, 2024, Occasional Sales and transfers, each punishable by a maximum penalty of $1,000:

    a. A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery. Such transfer or delivery includes either of the following:

        i. Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control, OAC Rule 4729:5-3-09(E)(1); and/or

        ii. The sale, purchase, or transfer of a drug or an offer to sell, purchase, or transfer of a drug among hospitals or other health care entities that are under common control. Common control means the power to direct or cause the

direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise, OAC Rule 4729:5-3-09(E)(2)).

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

    a. Except as provided in paragraph (L) of this rule, all non-hazardous, non-sterile compounded drug preparations shall be prepared in accordance with United States pharmacopeia chapter <795>, OAC Rule 4729:7-3-03(A); and/or

    b. 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

    c. 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

    d. For all hazardous non-sterile and sterile compounded drug preparations, a prescriber shall comply with rule 4729:7-3-05 of the Administrative Code, OAC Rule 4729:7-3-03(D); and/or

    e. 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

f. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-03(F); and/or

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

i. Inspect and approve the compounding process, OAC Rule 4729:7-3-03(G)(1); and

ii. Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-03(G)(2); and/or

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

i. Verify the accuracy of:

1. Drug name, OAC Rule 4729:7-3-03(I)(3)(a); and/or
2. Drug strength and dosage form, OAC Rule 4729:7-3-03(I)(3)(b); and/or
3. Drug volume, OAC Rule 4729:7-3-03(I)(3)(c); and/or
4. Rate of administration, OAC Rule 4729:7-3-03(I)(3)(d); and/or
5. Route of administration, OAC Rule 4729:7-3-03(I)(3)(e); and/or
6. Expiration dates/times, OAC Rule 4729:7-3-03(I)(3)(f); and/or
7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-03(I)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-03(I)(4); and/or

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-03(I)(5); and/or

i. 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).

16. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021, each 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 training and competency of compounding personnel, OAC Rule 4729:7-3-04(A)(4); and/or

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

        vi. 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

        vii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-04(A)(7); and/or

        viii. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-04(A)(8); and/or

    b. 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

c. 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

d. Immediate-use compounded drug preparations shall be prepared in accordance with this rule except in an emergency, as documented in the medical record, when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, OAC Rule 4729:7-3-04(F); and/or

e. Except as provided in paragraph (G)(2) of this rule, 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 4729:7-3-04(G)(1); 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. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-04(K); and/or

h. 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

    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

i. 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

j. 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 strength and dosage form, OAC Rule 4729:7-3-04(N)(3)(b); and
2. Expiration dates/times, OAC Rule 4729:7-3-04(N)(3)(f); and/or
3. 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); and/or

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-04(N)(5).

17. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-3-06 of the OAC, as effective March 31, 2021, each 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. All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

1. Complies with the requirements of this rule, OAC Rule 4729:7-3-06(A)(2)(a); and
2. All paper records shall be scanned in full color via technology designed to capture information and reproduce it in an electronic medium presentable and usable to an end user, OAC Rule 4729:7-3-06(A)(2)(b); and
3. Contains security features, such as unique user names and passwords, to prevent unauthorized access, OAC Rule 4729:7-3-06(A)(2)(c); and
4. Contains daily back-up functionality to protect against record loss, OAC Rule 4729:7-3-06(A)(2)(d); and

iii. 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
2. Name, strength, and dosage form of the compounded drug, Rule 4729:7-3-06(A)(3)(b); and
3. Name and quantity of each ingredient, Rule 4729:7-3-06(A)(3)(c); and
4. If a controlled substance, the disposition of unused drug(s) and amount, Rule 4729:7-3-06(A)(3)(d); and
5. Date and time of preparation, Rule 4729:7-3-06(A)(3)(e); and
6. Beyond-use date of the compounded drug, Rule 4729:7-3-06(A)(3)(f); and
7. The positive identification of the personnel responsible for compounding the drug, Rule 4729:7-3-06(A)(3)(g); and
8. The positive identification of either of the following:

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

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

b. Records of disposal of compounded drugs, 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, the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:7-3-06(B); and/or

c. All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years:

    i. A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board, OAC Rule 4729:7-3-06(E)(1); and/or

    ii. Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs, OAC Rule 4729:7-3-06(E)(2).

18. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-01 of the OAC, as effective July 1, 2024, each punishable by a maximum penalty of $1,000: A terminal distributor of dangerous drugs shall dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317 (9/25/2023). The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (9/25/2023) shall be maintained for a minimum of three years and made readily retrievable, OAC Rule 4729:5-3-01(B)

19. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024, each 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

        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 Rule 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); and/or

        iii. Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:5-3-01 of the Administrative Code, OAC Rule 4729:5-3-06(C).

20. 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, each violation punishable by a maximum penalty of $1,000:

    a. Except as provided in paragraphs (F) and (G) of this rule, controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe to deter and detect unauthorized access:

        i. In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a prescriber or pharmacist if not being used by a prescriber, pharmacist or a licensed health care professional in accordance with paragraph (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule. All locks shall be kept in good working order with keys removed therefrom, OAC Rule 4729:5-19-03(B)(4); and/or

        ii. During non-business hours, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility, OAC Rule 4729:5-19-03(B)(5); and/or

        iii. Except as provided in paragraph (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule, only a prescriber or pharmacist shall be able to access the cabinet or safe.

1. A prescriber or pharmacist may provide a licensed health care professional with a temporary key for the purposes of accessing the cabinet or safe. A licensed health care professional shall return the key provided in accordance with this paragraph to the prescriber or pharmacist or to a secured location with restricted access (such as a lockbox) no later than the end of the provider's shift or if there is no longer a prescriber or pharmacist available to provide personal supervision, OAC Rule 4729:5-19-03(B)(6)(a); and/or

2. A prescriber or pharmacist may provide a licensed health care professional with a key, combination or access code for the purposes of accessing the cabinet or safe, if all the following conditions apply:

    a. The cabinet or safe is maintained in a room secured by a physical barrier with suitable locks that can only be unlocked by a prescriber or pharmacist, OAC Rule 4729:5-19-03(B)(6)(b)(i); and

    b. The room is locked during non-business hours or when there is no longer a prescriber or pharmacist available to provide personal supervision, OAC Rule 4729:5-19-03(B)(6)(b)(i)(i); and/or

3. Any other method approved by the board's executive director or the director's designee that provides effective controls and procedures to guard against theft and diversion, OAC Rule 4729:5-19-03(B)(6)(c); and/or

b. Except as provided in paragraph (G) of this rule, a licensed health care professional, acting within the scope of the professional's practice, may have access to controlled substances only under the personal supervision of a prescriber or pharmacist, OAC Rule 4729:5-19-03(C); and/or

c. 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

d. 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

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

    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

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).

21. 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, as effective February 4, 2021, 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 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

d. Records of controlled substance drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

    i. If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee, OAC Rule 4729:5-19-04(G)(1); and/or

    ii. If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient or the disposal of patient owned drug stock maintained in accordance with paragraph (G) of rule 4729:5-19-03 of the Administrative Code, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal, OAC Rule 4729:5-19-04(G)(2); and/or

e. Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, expiration date and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale, OAC Rule 4729:5-19-04(H).

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 <u>not</u> 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/alg/jrn

cc: Melinda Snyder, State Medical Board of Ohio, at: Melinda.Snyder@med.ohio.gov