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Steven W. Schierholt, Esq., Executive Dir.
Date: 4/21/2025
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SUMMARY SUSPENSION/NOTICE OF OPPORTUNITY FOR HEARING
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE

IN THE MATTER OF: **CASE NOS. A-2024-0469 & A-2025-0105**

Slimbolic DBA Slimbolic Weight Loss & Med Spa **License No. 02-60002573**
c/o Matt Elam & Sarah J. Bristow, APRN
67 Marydale Drive
Ste. B
Beavercreek, Ohio 45440

April 21, 2025

Dear Slimbolic DBA Slimbolic Weight Loss & Med Spa:

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Slimbolic DBA Slimbolic Weight Loss & Med Spa's (Slimbolic'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 Slimbolic'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 Slimbolic's license as a Terminal Distributor of Dangerous Drugs. Pursuant to Division (D)(1) of Section 4729.57 of the ORC, Slimbolic must immediately surrender license number 02-60002573 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. Slimbolic DBA Slimbolic Weight Loss & Med Spa, located at 67 Marydale Drive, Suite B, Dayton, Ohio, is a licensed TDDD under license number 02-60002573 and lists Sarah J. Bristow, APRN, [Ohio Board of Nursing license number APRN.CNP.16049] as the Responsible Person since May 23, 2024 and Katherine Russell, MD [State Medical Board of Ohio license number 35.142965] as the Responsible Person from August 26, 2023 to May 8, 2024. Matt Elam is listed as the owner.

ALLEGATIONS

1. On or about March 27, 2024, a Board Inspector and a Board Specialist (Board inspectors) conducted an inspection at Slimbolic, located at 67 Marydale Drive, Suite B, Dayton, Ohio. Due to the nature of the violations, the March 27, 2024, inspection led to three follow-up inspections in 2024. A fifth inspection was conducted on April 11, 2025. The results of the fifth inspection, coupled with Slimbolic's blatant and ongoing disregard for regulatory law, as detailed below, resulted in the Board issuing a summary suspension to Slimbolic.

2. The inspection conducted on March 27, 2024, resulted in 14 warnings requiring written responses and multiple additional warnings that did not require response, including but not limited to:

    a. The Responsible Person is not physically present at the clinic for a sufficient amount of time.

        i. It was reported that the Responsible Person, Dr. Katherine Russell, resides in Maine. She did not treat clinic patients, and she had never been physically present at the clinic. Staff indicated they were working on finding a replacement Responsible Person.

    b. Personally furnished dangerous drugs: lack of United States Pharmacopeia (USP) Chapter 797 compliance, non-compliant labels, lack of personal supervision to prepare drugs for personally furnishing, and lack of supervision to distribute personally furnished drugs.

        i. There was no prescriber supervising the compounding, preparation and/or distribution of the drugs that were personally furnished. There was no prescriber performing the "final check" of the compounded drug.

ii. Four insulin syringes were drawn up with translucent liquid inside and non-compliant labeling. Staff explained these were awaiting patient pickup as "take home doses" of injectable semaglutide and had been prepared from multi-dose vials in the hallway of the clinic. The hallway was not sterile; therefore, this process was not compliant with USP Chapter 797.

iii. Matt Elam, the clinic owner, was told to immediately cease personally furnishing due to the lack of supervision by a prescriber and the lack of appropriate facilities to do so.

c. Non-hazardous drugs compounded by a prescriber.

i. There was no prescriber oversight.

ii. The clinic received non-patient specific semaglutide, tirzepetide, lipo mino, and tri-immunity boost from outsourcers. From there, the nurses would draw-up doses into syringes for personal furnishing. This compounding was not performed in a sterile environment.

iii. Staff had not received any specific training from the Responsible Person for compounding. There were no policies and no training records.

iv. Board inspectors observed 2 ml and 5 ml empty sterile vials in the medication cabinet. A nurse and Mr. Elam indicated they were not sure why the clinic had the vials. The inspector was concerned these vials were used for repackaging sterile drugs into patient-specific vials for personal furnishing. Staff denied this occurred at the clinic.

d. Pre-printed orders – the clinic was using non-compliant pre-printed orders for drug administration and non-compliant electronic prescription ordering.

i. Pre-printed orders were observed for semaglutide, tirzepetide, Zofran, and IV hydration.

1. There were only specific doses and frequencies for semaglutide and tirzepetide.

2. The pre-printed order also indicated injections of vitamins up to 1 ml/week were authorized, but did not contain specifics.

3. The orders did not indicate a specific drug, dose, quantity, or frequency, as required.
4. The prescriber's signature was electronic, not manual (this is not compliant with positive identification (ID)).

e. Records of personally furnishing were not compliant.

i. Inspectors observed a binder containing records of personally furnished medication pick up. There was no record of preparing drugs to be personally furnished, as required.

There was only a record of the pick-up transaction. The medication strength, quantity, and dose were not clearly marked on the form.

ii. Records observed to be missing altogether: patient address and date of birth and positive ID of the prescriber personally furnishing.

iii. The clinic was told to cease personally furnishing drugs effective immediately. If the clinic obtains a prescriber who will provide prescriber oversight, the clinic was told to obtain a new form that is compliant.

f. Records of in-office drug administration were not compliant.

i. The records were missing drug strength, dose, and date of birth of the patient.

ii. The records did not clearly delineate whether the drug was administered or personally furnished.

iii. Observed a binder labeled with tabs for injection Medication Administration Records (MARs). Of note, due to staff turnover, the process for documenting is inconsistent. Prior staff were documenting administration in the MAR binder; newer staff have documented personally furnishing and administration all in one location.

iv. Records observed to be missing altogether: drug strength and date of birth for the patient being administered the drug.

g. The clinic did not retain all required records. The records that were retained were not stored at the clinic, and notice had not been submitted to the Board for off-site storage.

i. There were no records of drug disposal for non-controlled dangerous drugs. Staff stated disposal was performed without documentation.

ii. Mr. Elam stated he does not always keep records of packing slips or receipts of drugs. His wife keeps track of billing and stores some documents at home.

iii. The clinic stated records would be moved to the clinic by the end of April 2024.

h. Adulterated drug stock was comingled with the active drug stock.

i. Board inspectors observed expired insulin syringes containing a translucent liquid (likely injectable semaglutide prepared from multi-dose vials in the hallway) that were adulterated since they were not in compliance with multiple rules.

i. The clinic did not complete an annual query of the board's online roster prior to purchase of dangerous drugs at wholesale.

j. Refrigerators and/or freezers used for storage of drugs and devices did not record temperatures daily. There were no temperature logs maintained after December 29, 2023. There were no temperatures recorded on weekends or days the clinic was closed.

3. The second inspection was conducted on May 1, 2024. This inspection resulted in five warnings requiring written responses and multiple additional warnings that did not require responses, including but not limited to:

   a. The Responsible Person is not physically present at the clinic for a sufficient amount of time.

      i. Mr. Elam explained that he was not a licensed healthcare professional, stated that Dr. Russell was still the Responsible Person; a replacement Responsible Person had not been chosen. He confirmed that she was still never physically onsite.

   b. Pre-printed orders – the clinic was using non-compliant pre-printed orders for drug administration and non-compliant electronic prescription ordering.

      i. Pre-printed orders with patient protected health information (PHI) were emailed between the clinic and Dr. Whitaker Smith (license no. 35.069231), who prescribed from Tennessee. Dr. Smith was the only prescriber who prescribed for the clinic's weight loss patients (semaglutide or tirzepatide). Dr. Smith and Mr. Elam corresponded and sent/received orders to the clinic via Gmail email accounts because Dr. Smith did not have access to Slimbolic's electronic medical record (EMR) system. The orders did not have positive ID.

      ii. Once Mr. Elam received Dr. Smith's email with a signed pre-printed order (containing PHI), he entered the prescription into the pharmacy's website account for Slimbolic which was pre-populated with various drugs/strengths/doses/directions. The information entered by Mr. Elam did not match Dr. Smith's prescription, rather Mr. Elam stated he made selections on the website he felt were closest to Dr. Smith's order. Once the prescription arrived at the clinic, Mr. Elam affixed a clinic-made label over the top of the pharmacy label to revert the drug dose and directions back to Dr. Smith's prescribed amount. This was altering the prescription dispensed by the pharmacy and was done without the pharmacy's permission and/or Dr. Smith's knowledge. This constitutes misbranding.

      iii. Mr. Elam was told to cease using the ordering website. Education was provided regarding compliant methods of oral, facsimile, and electronic prescription transmission.

   c. Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug were not kept confidential.

      i. Records provided to the Board as written responses to the 3/27/2024 inspection included pickup station logs, where patients sign to indicate their medication was

picked up. The log is a continuous list and displays other patient names, dates of birth, drug names/strengths/dosages.

d. The clinic did not retain all required records. The records that were retained were (still) not stored at the clinic.

   i. After the first inspection, the clinic stated records would be moved to the clinic by the end of April 2024. The records had not been relocated to the clinic.

   ii. Mr. Elam was relying on the online wholesaler accounts to store the required information; however, when Board inspectors asked to see the account(s), the required information was not present.

4. The third inspection was conducted on May 7, 2024. This inspection resulted in two warnings requiring written responses and multiple additional warnings that did not require response, including but not limited to:

   a. The Responsible Person is not physically present at the clinic for a sufficient amount of time.

      i. Mr. Elam explained that Dr. Russell had still never been onsite and Dr. Smith- a doctor Mr. Elam had asked to be the Responsible Person- had declined the role.

      ii. Mr. Elam stated he would continue his search for a Responsible Person.

      iii. On or about May 8, 2024, a Board inspector spoke with Dr. Russell who explained Mr. Elam approached her to fulfill the role of Responsible Person and told her she would be utilized for guidance and advice. She would not have accepted the role if she was made aware of the responsibilities. She removed herself as Responsible Person later that day.

      iv. Mr. Elam submitted a Change of Responsible Person form on or about May 22, 2024 naming Sarah Bristow, APRN, as Responsible Person of Slimbolic.

   b. Pre-printed orders and electronic prescribing– the clinic was still using non-compliant pre-printed orders for drug administration and non-compliant electronic prescription ordering.

      i. Mr. Elam and Dr. Smith continued to email pre-printed orders containing PHI because Dr. Smith still did not have access to Slimbolic's EMR.

      ii. Once received by the clinic, nurses were transcribing the pre-printed orders onto another written pre-printed order form which was sent via facsimile without a prescriber's wet-ink signature.

      iii. Mr. Elam was told to stop emailing PHI and stop the use of nurse-transcribed facsimile order forms. Education was once again provided.

c. Records and protocol of in-office drug administration. Nurses administered doses of semaglutide and tirzepatide in the clinic without a documented order from a prescriber. The only documented prescriber orders were sent to the pharmacy for dispensing.

   i. Dr. Smith would send one set of orders. However, clinic staff would sometimes administer the first dose on site from clinic stock and then also send the entire order (from Dr. Smith) to the pharmacy as a prescription (this would include the already administered dose). This is not compliant. Two sets of orders would be required in this situation.

   ii. Other times, the on-site administration would begin when the clinic received the patient-specific prescription from the pharmacy and the initial dose was administered from the patient specific prescription.

d. Pick-up station violations.

   i. The clinic was acting as a pick-up station- the patient's prescription was sent to an out of state pharmacy then mailed to the clinic for patient pickup (instead of the patient's address). This occurred despite no clear and convincing evidence that delivery of the prescription to the patient would result in danger to the public health or safety or result in danger to the patient, as required by rule to act as a pick-up station.

   ii. Slimbolic was "upcharging" patients at the time of pickup for the medications dispensed by the pharmacy. The clinic was charged $107 by the pharmacy, but Slimbolic charged the patient $199 with no itemized bill explaining the charges. Staff stated a new itemized bill would be implemented by June 2024.

e. Drug storage while unlicensed by the Board. A review of records requested as part of the May 7, 2024 inspection showed Slimbolic served as a pick-up station for at least 374 prescriptions while not licensed as a TDDD with the Board from on or about March 2023 until issuance of the license on August 26, 2023. Mr. Elam explained the clinic did not retain all records of prescriptions received, so the number of prescriptions could not be confirmed.

5. The fourth inspection was conducted on September 25, 2024. This inspection resulted in five warnings requiring written responses and multiple additional warnings that did not require response, including but not limited to:

   a. Responsible Person – APRN Bristow was still the Responsible Person. It was reported that she was physically on site every couple of weeks and she was last there about two weeks before the inspection.

      i. Board inspectors were unable to report whether APRN Bristow was present a sufficient amount of time; however, due to the multiple warnings issued- many of them repeat violations- it appeared there was not enough supervision provided.

b. Pre-printed orders – the clinic was still using non-compliant pre-printed orders for drug administration and non-compliant electronic prescription ordering.

   i. Despite written warnings and education provided at two inspections, Mr. Elam and Dr. Smith continued to exchange PHI, including signed prescriber orders, via email.

   ii. Dr. Smith was never granted access to Slimbolic's EMR and electronic prescribing was never implemented despite the clinic's plan to do so in June 2024.

   iii. The process was outlined by Mr. Elam. He explained the out of state prescriber would print the pre-printed order form, evaluate the patient via telehealth, complete the pre-printed prescription, scan the form, and email it back to the clinic where clinic staff would transcribe the prescriber's order into the pharmacy's website account, to be dispensed patient-specific for either patient delivery or clinic delivery.

   iv. Mr. Elam- who is not a licensed healthcare professional- transmitted prescriptions electronically to pharmacies without providing his name. Mr. Elam, and nurses, would log into Dr. Smith's account as "Dr. Smith" and would not use their own profiles. Therefore, it appeared as if Dr. Smith had transmitted the prescriptions himself.

c. Records and protocol of in-office drug administration. Despite previous warnings and education provided, nurses continued to administer doses of semaglutide and trizepatide at the clinic without a documented order from a prescriber. The only documented prescriber orders were sent to the pharmacy for dispensing.

   i. Clinic staff would administer the first dose on site, on the day of the patient's appointment. There was no documented prescriber order for this initial dose, and the clinic was creating an "extra" order which was not approved by Dr. Smith.

d. Pick-up station violations.

   i. Despite the previous warning and education provided in May 2024, Slimbolic continued to "upcharge" patients who received pharmacy-dispensed prescriptions. The clinic was charged $55 by the pharmacy for a prescription, but Slimbolic charged the patient $267. There was no itemized bill explaining the charges, despite a response provided to the Board explain an itemized bill would be provided beginning in June 2024.

e. Adulterated drug stock was comingled with the active drug stock.

   i. Board inspectors observed patient-specific pickup station multi-dose vials were administered at the clinic, but the vials did not include a date opened or beyond-use date (BUD) applied. A clinic stock multi-dose vial of semaglutide had a sticker to indicate the date to discard, but the writing was smeared and illegible. These vials were adulterated.

f. The clinic did not complete an annual query of the Board's online roster prior to purchase of dangerous drugs at wholesale, from a new wholesaler, despite being warned during the first inspection.

6. On or about May 8, 2024, a Board inspector spoke with Dr. Katherine Russell, the clinic's Responsible Person. She stated she became medical director at Slimbloic in September 2023 through a company called Doctors for Providers. It was advertised as a "side job" where she would be contacted for advice and guidance. She had not been in contact with Mr. Elam between September 2023 and May 1, 2024, after the second Board inspection. She had never been onsite at the clinic. Dr. Russell submitted her removal as Slimbolic's Responsible Person that day.

7. On or about May 8, 2024, a Board inspector spoke with Dr. Whitaker Smith. He stated he connected with Slimbolic through a staffing agency. He began treating Slimbolic patients in approximately August 2023 and estimated he saw between three and eight Slimbolic patients per day. He was not aware of prescriptions being sent to the pharmacy with different doses and instructions than he prescribed. He was not aware of clinic staff altering the pharmacy's label by placing a different label on the vials.

8. On or about April 11, 2025, a fifth inspection was conducted at Slimbolic by a Board inspector and Board specialist (Board inspectors). Upon arrival, the Board inspectors were greeted in the front lobby area by Matt Elam, owner of Slimbolic. Mr. Elam was the only employee present. A Board agent arrived after the inspection started. The following was discovered by the Board inspectors during the inspection:

   a. Vials for injection use from "Alpha BioMed" were observed in a refrigerator. Alpha BioMed is not a legitimate wholesale drug distributor or drug manufacturer and is not licensed in Ohio. Investigation revealed Alpha BioMed does not have an FDA manufacturer registration.

   b. The Alpha BioMed vials observed included:

      i. Two vials in a bag labeled for "Mr. Elam" as personally furnished from Slimbolic, including: one vial labeled "Reta GLP-3" and one vial labeled "2X blend (tesamorelin/ipamorelin)".

      ii. One vial labeled "Sema GLP-1" was not labeled for a patient and not in a bag.

      iii. A bag containing prepared drug to be personally furnished was labeled for patient GW.

         1. The labels were non-compliant and did not include the date furnished or the address of the prescriber.

         2. Mr. Elam's "Reta", later discovered to be retatrutide, labeled dose contradicted the dose documented in his chart.

a. These are repeat violations from previous inspections.

c. When questioned about the Alpha BioMed products, Mr. Elam explained they were biologics and peptides, not compounded products.

i. He could not provide an eLicense query for Alpha BioMed but stated they are a manufacturer. He said Slimbolic purchased directly from Alpha BioMed to avoid Eli Lilly lawsuits.

d. Mr. Elam explained the Alpha BioMed drugs were all powders (vs. liquids) and pointed to several bacteriostatic water vials on his desk. He explained he reconstitutes the powders prior to use or personally furnishing.

i. He removed a vial of Alpha BioMed drug in powder form from his desk drawer.

ii. When asked to provide all medication products at the clinic, he produced 20 additional vials from his desk and five bags of patient-labeled drugs prepared to be personally furnished.

e. After all drugs were produced by Mr. Elam, drugs purported to be the following were removed from the clinic by Board inspectors:

i. 6 retatrutide vials

ii. 13 semaglutide vials

iii. 3 tirzepatide vials

iv. 7 “2X blend (tesamorelin/ipamorelin)” vials

1. Note: Retatrutide is not a Food and Drug Administration-approved medication. During the time of use at Slimbolic it was undergoing Phase III trials. Slimbolic was not part of these Phase III trials.

2. Each of these vials were labeled as “physician use only” but were not labeled as dietary supplements nor prescription drugs.

f. It was learned that these drugs were being administered at the clinic as well as personally furnished to patients.

9. The inspection of Slimbolic conducted by Board inspectors on April 11, 2025, resulted in 12 warnings requiring a written response and an additional warning that did not require a written response, including:

a. The clinic did not have a Responsible Person present a sufficient amount of time. The Responsible Person, Sarah Bristow, APRN, has been the Responsible Person since May 23,

2024. She is at the clinic once every three weeks for a few hours each visit. While at the clinic, she does not see patients. This is a repeat violation from previous inspections.

b. The clinic did not complete an eLicense query when ordering dangerous drugs- including drugs for injection labeled Reta, Sema, Tirz, and 2x Blend- at wholesale from Alpha BioMed. This is a repeat violation from previous inspections.

c. Personally furnished drug labels did not contain the required information. Personally furnished drugs were observed to be missing the date furnished and the address of the prescriber. One drug was observed with the incorrect dose/directions.

d. Plastic caps were observed in a medication supply closet. Mr. Elam explained the caps were to cap syringes of Lipo-Mino-Mix so patients could take them home for injection use. Slimbolic had no record of personally furnishing signed by a prescriber. Mr. Elam confirmed the syringes were furnished without a prescriber providing supervision. Note: Lipo-Mino-Mix is a compounded dangerous drug when pre-filled into syringes in a clinic setting.

e. Prescriber orders documented in patient charts did not match the dose documented as either administered or personally furnished. Additionally, there was not always an order or protocol for drugs administered by a health care professional who is not a prescriber. Board inspectors observed the following:

   i. Patient TB had an order for 1 mg semaglutide, weekly.

      1. The dose documented as administered on 3/28/2025 was 2.5 mg.

   ii. Patient CS had an electronic chart order for 2.5 mg (50 units) semaglutide weekly.

      1. The dose documented as administered on 3/28/2025 was 2.5 mg (100 units).

      2. Neither the order nor the administration log had the drug concentration documented.

   iii. Prescriber order stated “Retatrutide starting dose SQ weekly x 4 weeks" and “"Will start retatrutide and titrate as per schedule".

   iv. Mr. Elam was unable to retrieve medication orders from prescribers in the electronic medical record (EMR) when asked to do so. He demonstrated a lack of knowledge of the EMR system and repeatedly stated “I am not sure where to find that.”

   v. Due to his inability to locate prescriber orders in the EMR system(s), Mr. Elam was asked how he or Slimbolic’s nursing staff knew to prepare drugs to be personally furnished. He was unable to provide an answer. There was no explanation provided for the dose discrepancy.

f. A prescriber is not personally furnishing drugs; non-prescriber clinic staff is conducting all aspects of the personally furnishing. A prescriber is not providing oversight for the compounding of personally furnished drugs and although a prescriber may delegate an individual(s) to distribute the drugs (while providing supervision), the drugs must be personally furnished by the prescriber. There is no prescriber involved in any of these processes at the clinic and there is no prescriber providing the medication validation, or "final check."

   i. The clinic is drawing up syringes of Lipo-Mino and sending them home with patients for at-home injection. Nurses are preparing syringes when there is no prescriber is on site. There is no prescriber verifying the immediate-use compounded products and the clinic does not have facilities to allow the pre-filling of syringes.

   ii. This is a repeat violation from previous inspections.

   iii. The clinic is also personally furnishing vials of "sema GLP-1," "tirz GLP-2," "Reta GLP-3," and "2x blend" without a prescriber.

g. Records of personally furnishing did not contain the required information.

   i. Records of personally furnished drugs did not contain the positive identification of the prescriber who personally furnished the drug.

      1. The clinic maintained a pick-up log that contained the initials of the nurse who provided the personally furnished drug to the patient and (sometimes) the signature of the patient picking up the drug.

h. Refrigerators used for storage of drugs and devices did not record temperatures daily.

   i. The paper temperature logs were incomplete, beginning April 20, 2024. There were no temperatures recorded during long periods of time. For example, there were no entries recorded from August 15, 2024 to August 31, 2024. This was a repeat violation from previous inspections.

i. Observed patient specific medications that were packaged for personally furnishing stored in a refrigerator with food.

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 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

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).

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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).

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 sections 2925.23(A) of the ORC, illegal processing, each, a felony of the fourth degree, each punishable by a maximum penalty of $10,000 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of sections 2925.23(B) of the ORC, illegal processing, each, a felony of the fifth degree, each punishable by a maximum penalty of $7,500 if committed by an organization.

5. 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.

6. Such conduct as set forth in the Allegations Section, if proven, each 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.

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 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. A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site, OAC Rule 4729:5-2-01(E)(5); and/or

   c. 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. 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).

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. 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. 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

    f. 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

    g. 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. 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. 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

f. 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

g. Commission of an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed, OAC Rule 4729:5-4-01(B)(14); and/or

h. 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

i. 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 4729:7-3-03 of the OAC, as effective March 31, 2021, 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. 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

d. 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

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

f. 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

g. 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).

14. 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 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 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. 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 compounding process involves the simple transfer of not more than three commercially manufactured packages of sterile, non-hazardous drugs from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device, OAC Rule 4729:7-3-04(B)(1); and/or

        ii. Personnel shall adhere to appropriate aseptic technique, including all the following:

            1. Before beginning compounding activities, personnel shall perform a thorough hand-hygiene procedure, OAC Rule 4729:7-3-04(B)(2)(a); and

2. Compounding personnel shall don gloves prior to engaging in compounding activities, OAC Rule 4729:7-3-04(B)(2)(b); and/or

iii. If not immediately administered, the finished compounded drug preparation shall be regularly monitored by compounding personnel to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug preparations, and direct contact of outside surfaces, OAC Rule 4729:7-3-04(B)(3); and/or

iv. 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

2. For preparations of buffered lidocaine containing antimicrobial preservatives, no later than twelve-hours following preparation of the drug, OAC Rule 4729:7-3-04(B)(4)(b); and/or

v. If administration has not begun within the beyond-use dating described in paragraph (B)(4) of this rule, the drug shall be promptly, properly, and safely disposed. Records of disposal shall be maintained in accordance with rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(B)(5); and/or

vi. 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

vii. 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 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

e. 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

f. 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

g. 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

h. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-04(K); and/or

i. 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

j. 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

k. 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).

15. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-3-06 of the OAC, as effective March 31, 2021, 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. 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).

16. 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 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.

   i. 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).

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

18. 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, as effective March 1, 2020, 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

       ii. Directions for use, OAC Rule 4729:5-19-02(A)(4); and

       iii. Date furnished, OAC Rule 4729:5-19-02(A)(5); and

       iv. 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).

    b. Except as provided in paragraph (E)(2) of this rule, only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification, OAC Rule 4729:5-19-02(E)(1); and/or

    c. A prescriber may designate a licensed health care professional acting within the scope of the professional's practice and, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber or a pharmacist in accordance with paragraph (E)(2) of this rule, OAC Rule 4729:5-19-02(F)(1); and/or

d. A prescriber may designate an unlicensed person, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber or a pharmacist in accordance with paragraph (E)(2) of this rule, OAC Rule 4729:5-19-02(F)(2);

e. Provision of dangerous drugs. A prescriber may delegate an individual or individuals to distribute dangerous drugs personally furnished by a prescriber or pharmacist if all the following apply:

i. A prescriber or pharmacist provides personal supervision, OAC Rule 4729:5-19-02(H)(1)(a); and

ii. Counseling is offered in accordance with paragraph (G) of this rule, OAC Rule 4729:5-19-02(H)(1)(b); and

iii. This task may be delegated in accordance with applicable state laws and rules, OAC Rule 4729:5-19-02(H)(1)(c).

f. Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug, OAC Rule 4729:5-19-02(K).

19. 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. Only a prescriber shall have access to uncompleted prescription blanks used for writing a prescription. Uncompleted prescription blanks shall be secured when not in use, OAC Rule 4729:5-19-03(D); and/or

b. 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

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

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

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

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

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

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

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

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

f. Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(O).

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

i. For temperature logs, either:

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

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

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

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

e. Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration, and either:

i. For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug, OAC Rule 4729:5-19-04(E)(1)(a); and/or

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

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

f. 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

g. 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.

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 4729:5-19-04(J)(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 4729:5-19-04(J)(2).

21. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-14 of the OAC, as effective December 1, 2020, each violation punishable by a maximum penalty of $1,000: The state board of pharmacy may restrict a site from acting as a pick-up station if it has clear and convincing evidence that the activities of the pick-up station present the following:

a. Danger to public health or safety, OAC Rule 4729:5-5-14(C)(1); or

b. Danger to the patient, OAC Rule 4729:5-5-14(C)(1).

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/alg/jrn

cc: Melinda Snyder, State Medical Board of Ohio, at: melinda.snyder@med.ohio.gov
David Geiger, Ohio Board of Nursing, at: david.geiger@nursing.ohio.gov