Rules and Resolutions – October 2024

Resolutions

Indicates resolutions was authorized by the Board President in accordance with a Board resolution adopted on May 5, 2020.

1) Sale of Non-Controlled Medications by Local Health Departments*

The Board hereby authorizes a local health department, as defined in rule 4729:5-3-09 of the Administrative Code, to engage in the occasional sale of non-controlled dangerous drugs to any other local health department in this state holding a terminal distributor of dangerous drugs. Each local health department shall comply with the applicable recordkeeping rules set forth in division 4729:5 of the Administrative Code. (Authorized 9.6.2024)

2) Appointment of the Controlled Substance Advisory Committee

Pursuant to OAC 4729-2-02, the Ohio Board of Pharmacy hereby appoints the following members of the Controlled Substance Advisory Committee:

- Ara Mekhjian, Ohio Attorney General's Office.
- Miranda Williams, Ohio Department of Health.
- Tim Bodle, Ohio Department of Mental Health and Addiction Services.
- Dr. Dennis Summers, Ohio Department of Agriculture.
- James Smith, Ohio Department of Public Safety.
- Dr. Thomas Gilson, Cuyahoga County Medical Examiner.
- Natalie Rine, PharmD, Director of Central Ohio Poison Center – Nationwide Children's Hospital
- Jason Holdren, Gallia County Prosecutor.
- Dr. Hannah Hays, medical toxicologist, Nationwide Children's Hospital.
- Dr. Kenneth Yeager, Ohio Chemical Dependency Board.

Rules

Rule 4729:1-3-02 | Immunization administration by pharmacists. (AMEND)

(A) A course in the administration of immunizations developed pursuant to division (B)(1) of section 4729.41 of the Revised Code shall meet the following requirements:

(1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of immunizations.

(2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the United States department of health and human services.

(3) The course shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(4) The course must be a minimum of five hours in length and include the following:

(a) A review of immunology that includes a discussion of the body's immune system reaction to immunizations.

(b) A review of each immunization recommended by the **advisory** committee on immunization practices of centers for disease control and prevention in the United States department of health and human services ~~**(8/5/2022)**~~ **(6/28/2024)** that includes the following:

(i) Disease states associated with the immunization;

(ii) Type or nature of activity of the immunization;

(iii) Administration schedules;

(iv) Routes of administration;

(v) Injection sites;

(vi) Dosages;

(vii) Monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;

(viii) Patient populations;

(ix) Precautions and contraindications; and

(x) Proper storage requirements for the immunization.

(c) A review of sterile technique in injectable dosage preparation and administration.

(d) A minimum of one hour of instruction and physical participation in administration techniques.

(e) A review of the proper disposal procedures for contaminated needles and immunizations.

(f) A review of the proper procedures for accidental needle sticks.

(5) The course must provide a method to evaluate the successful comprehension of the content.

(6) The course must provide a method to demonstrate the participant has successfully completed the course.

(B) Courses on immunization administration may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.

(C) Failure to adhere to the standard of care for administration of an immunization shall be considered a violation of this rule and may subject a pharmacist to discipline in accordance with rule 4729:1-4-01 of the Administrative Code.

(D) Pursuant to section 4729.41 of the Revised Code, a physician-established protocol for the administration of immunizations shall include the following:

(1) For each immunization authorized:

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Dosage;

(e) Administration schedules;

(f) Routes of administration; and

(g) Injection sites.

(2) The length of time the pharmacist**, ~~or a~~** pharmacy intern**, certified pharmacy technician or registered pharmacy technician** under the direct supervision of a pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist**, ~~or~~** pharmacy intern**, certified pharmacy technician or registered pharmacy technician** to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) A method to notify an individual's primary care provider or the applicable board of health within thirty days after administering an immunization, except for influenza immunizations administered to individuals eighteen years of age and older.

(5) The locations that a pharmacist**, ~~or~~** pharmacy intern**, certified pharmacy technician or registered pharmacy technician** under the direct supervision of a pharmacist may engage in the administration of immunizations.

(E) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis.

(1) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector or employee of the state board of pharmacy.

(F) Upon the request of the state board of pharmacy, a pharmacist or terminal distributor of dangerous drugs shall immediately provide the protocols for immunizations. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist or terminal distributor for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has granted approval.

~~**(G) A pharmacist may administer the following immunizations in accordance with section 4729.41 of the Revised Code and this rule:**~~

~~**(1) In the case of administer to an individual who is seven five years of age or older but not more than thirteen years of age, administer to the individual an immunization for any of the following:**~~

~~**(a) Influenza;**~~

~~**(b) COVID-19;**~~

~~**(c) Any other disease, but only pursuant to a prescription.**~~

~~**(2) In the case of an individual who is thirteen years of age or older, administer to the individual an immunization for any disease, including an immunization for influenza or COVID-19.**~~

(G) A pharmacist, in accordance with section 4729.41 of the Revised code and this rule, may administer to an individual who is five years of age or older an immunization for any disease, including an immunization for influenza or COVID-19.

(H) A pharmacist shall obtain informed consent pursuant to rule 4729:5-5-04 of the Administrative Code to administer an immunization.

(I) Immunization records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.

(J) A pharmacist shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

(K) For each immunization administered to an individual by a pharmacist, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist shall notify the individual's primary care provider or, if the individual has no primary care provider, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication;

(7) Reporting to the state's immunization registry; or

(8) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(L) For each immunization administered by a pharmacist to an individual who is younger than eighteen years of age, the pharmacist shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.

~~(L)~~ **(M)** A pharmacist administering immunizations in accordance with this rule shall receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association**, American safety and health institute,** or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person or electronic hands-on training component.

~~(M)~~ **(N)** A pharmacist who completed a course in the administration of immunizations that complied with the training requirements in effect immediately prior to the adoption of this rule shall be deemed in compliance with division (B)(1) of section 4729.41 of the Revised Code.

~~(N)~~ **(O)** A pharmacist shall maintain the following records on file at the location(s) where the pharmacist administers immunizations in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (A) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (M) of this rule.

~~(O)~~ **(P)** As part of engaging in the administration of immunizations or supervising an individual authorized to administer immunizations, a pharmacist may administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the pharmacist or other authorized individuals under the supervision of the pharmacist.

Rule 4729:2-3-03 | Immunization administration by pharmacy interns. (AMEND)

(A) Pharmacy interns working under the direct supervision of a pharmacist may administer immunizations listed in paragraph (C) of this rule if an intern complies with the following:

(1) Successfully completes a course in the administration of immunizations that meets the requirements set forth in rule 4729:1-3-02 of the Administrative Code.

(2) Practices in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician that complies with the requirements of rule 4729:1-3-02 of the Administrative Code.

(3) Receives and maintains certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association**, American safety and health institute,** or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person or electronic hands-on training component.

(4) The supervising pharmacist has completed all of the training necessary to administer immunizations in accordance with rule 4729:1-3-02 of the Administrative Code.

(B) Failure to adhere to the standard of care for administration of an immunization shall be considered a violation of this rule and may subject a pharmacy intern to discipline in accordance with rule 4729:2-4-01 of the Administrative Code.

(C) A pharmacy intern working under the direct supervision of a pharmacist may administer the same immunizations authorized for pharmacist administration as authorized by section 4729.41 of the Revised Code and rule 4729:1-3-02 of the Administrative Code.

(D) A pharmacy intern shall obtain informed consent pursuant to rule 4729:5-5-04 of the Administrative Code to administer an immunization.

(E) A pharmacy intern shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

(F) For each immunization administered to an individual by a pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacy intern shall notify the individual's primary care provider or, if the individual has no primary care provider, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication;

(7) Reporting to the state's immunization registry; or

(8) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(G) For each immunization administered by a pharmacy intern to an individual who is younger than eighteen years of age, the pharmacy intern shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.

~~(G)~~ **(H)** A pharmacy intern shall maintain the following records on file at the location(s) where the pharmacy intern administers immunizations in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (A)(1) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (A)(3) of this rule.

Rule 4729:3-3-06 | Immunization administration by certified and registered pharmacy technicians. (AMEND)

~~**(A) A certified or registered pharmacy technician who meets the requirements of paragraph (B) of this rule and is working under the direct supervision of a pharmacist who meets the requirements of rule 4729:1-3-02, may do any of the following:**~~

~~**(1) In the case of administer to an individual who is seven five years of age or older but not more than thirteen years of age, administer to the individual an immunization for any of the following:**~~

~~**(a) Influenza;**~~

~~**(b) COVID-19;**~~

~~**(c) Any other disease, but only pursuant to a prescription.**~~

~~**(2) In the case of an individual who is thirteen years of age or older, administer to the individual an immunization for any disease, including an immunization for influenza or COVID-19.**~~

(A) A certified or registered pharmacy technician who meets the requirements of paragraph (B) of this rule and is working under the direct supervision of a pharmacist who meets the requirements of rule 4729:1-3-02 of the Administrative Code, may:

(1) Administer to an individual who is five years of age or older an immunization for any disease, including an immunization for influenza or COVID-19.

~~**(3)**~~ **(2)** The pharmacist on duty who is supervising the technician may prohibit, limit, or restrict the type of immunizations administered, including the age of the patient, by the technician.

(B) For a certified or registered pharmacy technician to be authorized to engage in the administration of immunizations, comply with all the following requirements:

(1) Complete a practical training program that meets the requirements set forth in paragraph (C) of this rule.

(2) Administer immunizations authorized by a physician-established protocol that meets the requirements of rule 4729:1-3-02 of the Administrative Code.

(3) Be authorized by the supervising pharmacist to administer immunizations. The supervising pharmacist may restrict the type of immunizations provided by a certified or registered technician.

(4) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association**, American safety and health institute,** or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in- person or, at a minimum, offer an in-person or electronic hands-on training component.

(5) The pharmacist on duty who is supervising the technician shall be on-site to administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the registered or certified pharmacy technician.

(6) The pharmacist on duty who is supervising the technician determines if the technician is competent to administer immunizations.

(C) A course in the administration of immunizations developed pursuant paragraph (B) of this rule shall meet the following requirements:

(1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of immunizations.

(2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the United States department of health and human services.

(3) The course shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(4) The course must be a minimum of six hours in length and include, at a minimum, the following topic areas:

(a) A review of immunology that includes a discussion of the body's immune system reaction to immunizations.

(b) A review of each immunization recommended by the **advisory** committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services **(6/28/2024)**~~**(8/5/2022)**~~:

(i) Disease states associated with the immunization;

(ii) Type or nature of activity of the immunization;

(iii) Administration schedules;

(iv) Routes of administration;

(v) Injection sites;

(vi) Dosages;

(vii) Monitoring and treatment of the patient for adverse reactions;

(viii) Patient populations;

(ix) Precautions and contraindications; and

(x) Proper storage requirements for the immunization.

(c) A review of sterile technique in injectable dosage preparation and administration.

(d) A minimum of one hour of instruction and physical participation in administration techniques.

(e) A review of the proper disposal procedures for contaminated needles and immunizations.

(f) A review of the proper procedures for accidental needle sticks.

(5) The course must provide a method to evaluate the successful comprehension of the content.

(6) The course must provide a method to demonstrate the participant has successfully completed the course.

(D) Courses on immunization administration may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.

(E) The pharmacy employing the technician shall ensure informed consent is obtained pursuant to rule 4729:5-5-04 of the Administrative Code prior to the administration of an immunization.

(F) The pharmacy employing the technician shall ensure the technician maintains the competency and skills necessary to safely administer immunizations. The pharmacy shall ensure the technician has initial and annual documented assessment of competency in immunization administration.

(G) Immunization records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.

(H) The pharmacy where a technician is administering immunizations in accordance with this rule shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

(I) For each immunization administered to an individual by a certified or registered pharmacy technician, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacy employing the technician shall be responsible for ensuring the notification of the individual's primary care provider or, if the individual has no primary care provider, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Reporting to the state’s immunization registry;

(7) Documented verbal communication; or

(8) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(J) For each immunization administered by a certified pharmacy technician or registered pharmacy technician to an individual who is younger than eighteen years of age, the certified pharmacy technician or registered pharmacy technician shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.

~~(J)~~ **(K)** The pharmacy employing a certified or registered technician authorized to provide immunizations in accordance with this rule, shall maintain, or have immediate access to, the following records on file at the location(s) where the pharmacy technician administers immunizations in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (C) of this rule;

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (B)(4) of this rule; and

(3) Proof of competency assessments as required in paragraph (F) of this rule.

~~(K)~~ **(L)** A pharmacist practicing within an outpatient pharmacy shall not supervise more than three pharmacy personnel engaged in the administration of immunizations pursuant to this rule and rule 4729:2-3-03 of the Ohio Administrative Code.

~~(L)~~ **(M)** A pharmacist supervising an immunization clinic outside of an outpatient pharmacy shall not supervise more than six pharmacy personnel engaged in the administration of immunizations pursuant to this rule and rule 4729:2-3-03 of the Ohio Administrative Code.

Rule 4729:5-3-04 | Verification of licensure prior to sale or purchase. (AMEND)

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

(1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code; or

(2) 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.

(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.

If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section 4729.51 of the Revised Code in making the purchase.

(C) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729:5-3-09 of the Administrative Code, the terminal distributor shall query the ~~**boards**~~ **board's** online roster (available on the ~~**boards**~~ **board's** website: www.pharmacy.ohio.gov) to determine if the purchaser is licensed as either:

(1) A terminal distributor of dangerous drugs.

For a limited terminal distributor of dangerous drugs license, a terminal distributor shall also review a current version of the **licensee's** ~~**licensees**~~ drug list to ensure the purchaser is authorized to possess the drugs ordered.

(2) A distributor of dangerous drugs in accordance with division 4729:6 of the Administrative Code.

(D) Paragraph (C) of this rule does not apply when a terminal distributor sells or distributes dangerous drugs at wholesale to any of the following:

(1) A terminal distributor, manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor that is located in another state, is not engaged in the sale of dangerous drugs within this state, and is actively licensed to engage in the sale of dangerous drugs by the state in which the distributor conducts business; or
(2) Any of the exempted persons described in section 4729.541 of the Revised Code.

(3) The sale, transfer, or distribution of dangerous drugs to an EMS organization from an institutional pharmacy or facility licensed as a terminal distributor of dangerous drugs that is owned or operated by a hospital for purposes of restocking an emergency medical services vehicle if the institutional pharmacy conducts an annual query to ensure the EMS organization is properly licensed as a terminal distributor of dangerous drugs.

(4) An intracompany transfer made in accordance with rule 4729:5-3-09 of the Administrative Code, if the entity engaged in the transfer conducts an annual query to ensure each location is properly licensed as a terminal distributor of dangerous drugs.

(E) A terminal distributor of dangerous drugs may make a sale of a dangerous drug to any of the exempted persons described in section 4729.541 of the Revised Code in accordance with rule 4729:5-3-09 of the Administrative Code and shall ensure the purchaser meets the exemption criteria. To confirm a purchaser meets the exemption criteria, the terminal drug distributor shall comply with ~~**the**~~ **all** the following:

(1) Provide the purchaser, in a manner determined by the board, the requirements in Ohio law of when a purchaser shall hold a license as a terminal distributor of dangerous drugs;

(2) If the purchaser is a prescriber, verify the prescriber is appropriately licensed in this state to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice;

(3) Require the purchaser who claims an exemption to the terminal distributor of dangerous drug licensing requirement to annually attest in writing, which may include an electronic signature, that the purchaser meets the licensing exemptions in section 4729.541 of the Revised Code; and

(4) Ensure that all attestations are maintained by the terminal distributor for a period of three years following the date the attestation is signed by the purchaser.

Rule 4729:7-1-01 | Compounding references and enforcement. (AMEND)

As used in this division and in agency 4729 of the Administrative Code:

(A) "The national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings" means publication number 2016-161 or any official supplement thereto **(~~March 10, 2020~~ May 9, 2023**).

(B) "United States Pharmacopeia Chapter <795>" or "USP <795>" means United States Pharmacopeia Chapter <795>**~~, USP 43-NF 38, or any official supplement thereto (March 10, 2020~~ (November 1, 2023**).

(C) "United States Pharmacopeia Chapter <797>" or "USP <797>" means United States Pharmacopeia Chapter <797>, **~~USP 43-NF 38, or any official supplement thereto (March 10, 2020~~ (November 1, 2023**).

(D) "United States Pharmacopeia Chapter <800>" or "USP <800>" means United States Pharmacopeia Chapter <800>**~~, USP 43-NF 38, or any official supplement thereto (March 10, 2020~~ (December 1, 2022**).

(E) The board may grant extensions to the requirements to comply with the references listed in this rule if a licensee can demonstrate the following:

(1) Significant hardship in meeting the requirements of the references; and

(2) Sufficient progress towards compliance with the references.

REMINDER: *The Board has already committed, via a resolution issued in December 2023, to a 1-year implementation window (e.g., a one-year effective date from the date the rule can be final filed) and the rule provides additional extensions for individuals who demonstrate hardship.*

Rule 4729:7-3-04 | Immediate-Use, Sterile Non-Hazardous Drugs Compounded by a Prescriber. (AMEND)

(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:

(1) Developing and implementing appropriate compounding procedures;

(2) Overseeing facility compliance with this rule;

(3) Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules;

(4) Ensuring training and competency of compounding personnel;

(5) Ensuring that compounded drug preparations maintain quality and sterility until administered;

(6) Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code;

(7) The proper maintenance, cleanliness, and use of all equipment used in compounding; and

(8) Ensuring aseptic technique for the preparation of all sterile compounded drugs.

(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:

(1) 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.

(2) Personnel shall adhere to appropriate aseptic technique, including all the following:

(a) Before beginning compounding activities, personnel shall perform a thorough hand-hygiene procedure; and

(b) Compounding personnel shall don gloves prior to engaging in compounding activities.

(3) 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.

(4) The beyond-use date for an immediate-use compounded drug preparation is as follows:

(a) Except as provided in paragraph (B)(4)(b) of this rule, no later than six-hours following preparation of the drug.

(b) For preparations of buffered lidocaine containing antimicrobial preservatives, no later than twelve-hours following preparation of the drug.

(5) 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.

(6) Unless administered immediately, the compounded drug preparation shall bear a label listing all the following:

(a) Except for preparations compounded in accordance with paragraph (G)(2) of this rule, patient identification information, including the patient's first and last name;

(b) The name and quantity of each ingredient;

(c) The beyond-use date and time prepared; and

(d) The name or initials of the person who prepared the compounded drug preparation.

(7) Immediate-use compounded drug preparations are for administration only and shall not be personally furnished by a prescriber.

(8) For an immediate-use compounded drug preparation administered via injection, a new sterile needle shall be used to administer the compounded drug preparations to the patient.

(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.

(D) Preparations that **do not meet the criteria listed in paragraph (B) of this rule** ~~**are deemed category two, medium-risk level, or high-risk level compounded drug preparations as defined in United States pharmacopeia chapter <797>**~~ shall not be prepared as immediate-use.

(E) Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code.

(F) 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.

(G)

(1) 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.

(2) A prescriber may compound preparations of buffered lidocaine containing antimicrobial preservatives for anticipated needs where multiple non-patient specific doses are produced in a single activity.

(H) Records of drug compounding shall be maintained pursuant to rule 4729:7-3-06 of the Administrative Code.

(I)

(1) Except as provided for in paragraph (I)(2) of this rule, this rule does not apply to a prescriber who is a veterinarian licensed under Chapter 4741. of the Revised Code. If preparing or handling hazardous drug preparations, a prescriber who is a veterinarian shall comply with rule 4729:7-3-05 of the Administrative Code.

(2) A veterinarian engaged in the compounding of immediate-use sterile drug preparations shall comply with the following:

(a) Unless administered immediately, the compounded drug preparation shall bear a label listing all of the following:

(i) Patient identification information, including the full name of the owner, if applicable, and the name or identification of the animal;

(ii) The name and quantity of each ingredient;

(iii) The date and time prepared; and

(iv) The name or initials of the person who prepared the compounded drug preparation.

(J) For hazardous compounded drugs, the prescriber shall comply with rule 4729:7-3-05 of the Administrative Code.

(K) A prescriber may designate an appropriately trained agent to prepare compounded drug preparations.

(L) For all compounded drugs prepared pursuant to this rule, a prescriber shall:

(1) Inspect and approve the compounding process; and

(2) Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered.

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

(1) 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; or

(2) 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.

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

(1) Verify patient identification using at least two identifiers (e.g., last name, medical record number, DOB, etc.).

(2) Confirm with the patient the patient's planned treatment, drug route, and symptom management.

(3) Verify the accuracy of:

(a) Drug name;

(b) Drug strength and dosage form;

(c) Drug volume;

(d) Rate of administration;

(e) Route of administration;

(f) Expiration dates/times;

(g) Appearance and physical integrity of the drugs.

(4) Indicate in the compounding record verification was completed.

(5) A licensed prescriber is on-site and immediately available.

…

Rule 4729:5-3-09 | Occasional sale and drug transfers. (AMEND)

(A) The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a commercially manufactured dangerous drug **that meets the definition of an exempted transaction in accordance with paragraph (J) of this rule** to a ~~**person**~~ **drug distributor** licensed in accordance with section 4729.52 of the Revised Code, terminal distributor of dangerous drugs **licensed in accordance with section 4729.54 of the Revised Code,** or any entity or person exempted from licensure as a terminal distributor of dangerous drugs **in accordance with section 4729.541 of the Revised Code** by any of the following:

(1) A pharmacy licensed as a terminal distributor of dangerous drugs~~.;~~

(2) A licensed terminal distributor of dangerous drugs that is not a pharmacy, but only as authorized in section 4729.51 of the Revised Code~~.;~~

(3) A local health department, as defined in paragraph (H) of this rule, licensed as a terminal distributor of dangerous drugs for the purpose of **either:**

(a) Improving or promoting public health within the department's jurisdiction, but only for the sale of non-controlled dangerous drugs; or

(b) Selling to another local health department licensed as a terminal distributor of dangerous drugs, but only for the sale of non-controlled dangerous drugs.

(4) A drug repository program pursuant to rule 4729:5-10-07 of the Administrative Code.

(B) The dosage units of all dangerous drugs distributed by the pharmacy pursuant to this rule shall not exceed five per cent of the total dosage units dispensed by the pharmacy during the same calendar year.

(C) The limits set forth in this rule do not apply to the following:

(1) A licensed terminal distributor of dangerous drugs as described in paragraph (A)(2) of this rule;

(2) Pharmacies that are also licensed to conduct sales of dangerous drugs in accordance with section 4729.52 of the Revised Code; and

(3) Drug repository programs pursuant to rule 4729:5-10-07 of the Administrative Code.

(D) The requirements of this rule do not apply to the transfer of dangerous drugs pursuant to paragraph (E) of this rule.

(E) 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:

(1) Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control.

(2) 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.

(F) Occasional sales by a licensed terminal distributor shall comply with the reporting requirements set forth in division 4729:8 of the Administrative Code.

(G) "Drug shortage," with respect to an occasional sale, means a drug on the United States food and drug administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.

(H) "Local health department' means a department operated by a board of health of a city or general health district or the authority having the duties of a board of health as described in section 3709.05 of the Revised Code.

(I) "Dosage unit" means any of the following:

(1) A single pill, capsule, ampule, or tablet;

(2) In the case of a liquid solution, one milliliter;

(3) In the case of a cream, lotion or gel, one gram; or

(4) Any other form of administration available as a single unit.

(J) “Exempted transaction” includes all the exemptions to the definition of a transaction pursuant to 21 U.S. Code § 360eee (11/27/2013).

Rule 4729:9-1-01.1 | Kratom. (RESCIND)

The following are classified as schedule I controlled substances:

(A) Mitragynine (to include synthetic equivalents as well as mitragynine naturally contained in the plant of the genus and species name: Mitragyna speciosa Korth, also known as kratom) its isomers, esters, ethers, salts and salts of isomers, esters and ethers.

(B) 7-Hydroxymitragynine (to include synthetic equivalents as well as 7- hydroxymitragynine naturally contained in the plant of the genus and species name: Mitragyna speciosa Korth, also known as kratom) its isomers, esters, ethers, salts and salts of isomers, esters and ethers.

NOTE: *Rule was originally filed in 07/05/2019 but placed on hold to allow the legislature to consider regulation.*

Rule 4729:9-2-01 | Standard Pharmaceutical Reference Manual. (NO CHANGE)

All editions, with cumulative changes, if any, of the following reference works are recognized and approved by the state board of pharmacy pursuant to section 2925.01 of the Revised Code:

(A) "Drug Facts and Comparisons";

(B) "Martindale: The Extra Pharmacopoeia";

(C) "Remington's Pharmaceutical Sciences";

(D) "United States Dispensatory";

(E) "United States Pharmacopeia/National Formulary (USP/NF)";

(F) "American Hospital Formulary Service Drug Information (AHFS Drug Information)";

(G) A controlled substance reference table compiled by the state board of pharmacy using any of the reference works listed in this rule. This table shall be made available on the board's web site (www.pharmacy.ohio.gov).

IMPORTANT REMINDER: *Please be advised that these are the standard pharmaceutical references the Board uses to calculate bulk-amounts for law enforcement. It does not limit or restrict pharmacies from using other references in the practice of pharmacy.*

Rule 4729:9-3-01 | Sale of Distribution of Ephedrine-Containing Products (NEW)

(A) As used in this rule, “ephedrine” is α -[-(Methylamino)ethyl]benzene-methanol; α-[1-(methylamino) ethyl]benzyl alcohol; 2-methylamino-1-phenyl-1-propanol; 1-phenyl-1-hydroxy-2-methylaminopropane; 1-phenyl-2- methylaminopropanol; α - hydroxy-β-methylaminopropylbenzene; a product which occurs in the Chinese herb Ma Huang (*Ephedra vulgaris, Ephedra sinica Stapf., Ephedra equisetina Bunge, Gnetaceae*) and in several other Ephedra spp. Isomeric forms include *d*- and *l*-ephedrine as well as *d*-and *l*-pseudoephedrine with *l*-ephedrine and *d*-pseudoephedrine as the naturally occurring isomers.

(B) Each of the following products containing ephedrine, its salts, its isomers, or the salts of its isomers is excepted from classification as a schedule V controlled substance:

(1) All products that contain the isomer known as pseudoephedrine or its salts, but do not also contain any of the isomer known as ephedrine or its salts.

(2) "Breathe Easy" herb tea.

(3) "Bronkaid Dual Action" caplets.

(4) "Hydrosal" hemorrhoidal ointment.

(5) "Primatene Dual Action Formula" tablets.

(6) "Primatene" tablets.

(7) "SnoreStop" tablets.

(8) Drug products listed in division (K)(1) of section 3719.44 of the Revised Code.

(C) Except as provided in paragraph (H) of this rule, any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall submit an application for the appropriate category III license in accordance with section 4729.52 of the Revised Code or 4729.54 of the Revised Code to conduct such activities in accordance with Chapters 3719. and 4729. of the Revised Code.

(D) Except as provided in paragraph (H) of this rule, schedule V products containing ephedrine may be sold at wholesale or retail, and must be maintained in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(E) Except as provided in paragraph (H) of this rule, a licensee who possesses any quantity of ephedrine or schedule V dangerous drug products containing ephedrine shall take an inventory pursuant to rule 4729:5-3-07 or 4729:6-3-06 of the Administrative Code.

(F) Except as provided in paragraph (H) of this rule, all licensees are required to keep records pursuant to Chapter 3719. of the Revised Code and agency 4729 of the Administrative Code shall maintain such records for ephedrine and schedule V drug products containing ephedrine.

(G) This requirements listed in paragraphs (C), (D), (E), and (F) do not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(1) of section 3719.44 of the Revised Code or paragraph (B) of this rule.

(H) A petition requesting that a drug product containing ephedrine be excepted by the board of pharmacy from being legally classified as a schedule V controlled substance stimulant may be submitted by any person engaged in the legitimate manufacture or wholesale sale of such products in the United States. The petition shall include the following information:

(1) Full name, address, and telephone number of the manufacturer.

(a) If incorporated, the petition must include copies of the incorporation papers and the names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the corporation's stock.

(b) If a proprietorship, the petition must include the name, address, date of birth, and social security number of the owner(s).

(c) If a partnership, the petition must include the names, addresses, dates of birth, and social security numbers of the partners.

(2) A description of the package sizes and the manner of packaging of the drug product.

(3) A limited number of samples of each dosage form marketed in the final marketed packages.

(4) The manner of distribution, advertising, and promotion of the product including the following:

(a) The full name and address of all accounts located in Ohio to which the products have been or will be distributed at wholesale based on other products marketed by the petitioner.

(b) Copies of all advertisements used to promote the product within the last twelve months shall be included with the petition. A list of the publications in which the advertisements appeared or will appear if not presently marketed. If the product has not yet been marketed, copies of other products marketed by the petitioner shall be submitted with the petition.

(5) A listing of all ingredients in the product, indicating the quantity of each ingredient, whether or not it has any therapeutic value, and its purpose for being included in the product.

Documentation of the therapeutic value of all active ingredients in the product shall be included with the petition.

(6) A list of all names the product is marketed or will be marketed under in the United States or any other country.

(7) Any information regarding the product's abuse or potential for abuse in the United States or other countries where the product is marketed or will be marketed under any of the names listed in paragraph (H)(6) of this rule.

(I) The board shall consider the following factors in determining whether a particular over-the-counter (OTC) drug product containing the schedule V controlled substance ephedrine is manufactured and distributed for legitimate use in a manner consistent with the pertinent OTC tentative or final monograph issued by the United States food and drug administration and in a manner that reduces the likelihood of inappropriate use and/or abuse:

(1) The package size and the manner of packaging;

(2) Distribution, advertising, and promotion of the product;

(3) Labeling and the name of the product;

(4) The potential, duration, scope, and significance of inappropriate use and/or abuse;

(5) Other facts as may be relevant to and consistent with public health and safety.

(J) The board shall remove a drug product exception for a particular drug product if it determines that the drug product is not manufactured and distributed for legitimate use and in a manner that reduces the likelihood of abuse.

New Rule Summary: *Combines all ephedrine related rules into a single rule. Rescinds the following rules that are now incorporated into this proposed rule:*

- *Rule 4729:9-3-01 | Definition of ephedrine.*
- *Rule 4729:9-3-02 | Licensure.*
- *Rule 4729:9-3-03 | Security, storage, and sale.*
- *Rule 4729:9-3-04 | Inventory.*
- *Rule 4729:9-3-05 | Records.*
- *Rule 4729:9-3-06 | Petitions for exception of ephedrine-containing products.*
- *Rule 4729:9-3-07 | Exceptions.*
- *Rule 4729:9-3-08 | Criteria to be considered in denying a petition for exception or removing a drug product exception.*

Rule 4729:5-10-01 | Definitions - drug repository programs. (NO CHANGE)

As used in Chapter 4729:5-10 of the Administrative Code:

(A) "Charitable pharmacy" has the same meaning as in section 3719.811 of the Revised Code.

(B) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(C) "Distributor of dangerous drugs" or "drug distributor" has the same meaning as in rule 4729:6-1-01 of the Administrative Code.

(D) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(E) "Drug repository program" means a program authorized to accept prescription drugs donated or given for the purpose of being dispensed or personally furnished to individuals who are residents of this state and meets eligibility standards established in this chapter.

(F) "Hospital" has the same meaning as in section 3727.01 of the Revised Code.

(G) "Institutional facility" has the same meaning as defined in agency 4729 of the Administrative Code.

(H) "Licensed health care professional" has the same meaning as in section 3715.872 of the Revised Code.

(I) "Nonprofit clinic" has the same meaning as in section 3715.87 of the Revised Code.

(J) "Orally administered cancer drug" means either of the following:

(1) An orally administered dangerous drug that is used to treat cancer or its side effects; or

(2) An orally administered dangerous drug that is used to treat the side effects of a dangerous drug used to treat cancer.

(K) "Original sealed and tamper-evident unit dose packaging" includes single unit dose packaging of oral medications from a manufacturer or a repackager registered with the federal food and drug administration, or from a pharmacy and includes injectables, topicals, and aerosols in the manufacturer's or repackager's unopened original tamper-evident packaging.

(L) "Prescription drug" has the same meaning as in section 3715.87 of the Revised Code.

(M) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

(N) "Underinsured" means any of the following:

(1) Having health care coverage or prescription drug coverage but having exhausted these benefits or being unable to afford any associated deductible, coinsurance, copayments, or similar charges for the drug prescribed; or

(2) Not having prescription drug coverage for the drug prescribed.

Rule 4729:5-10-02 | Eligibility requirements for a pharmacy, hospital, or nonprofit. (NO CHANGE)

A pharmacy, hospital, or nonprofit clinic may elect to participate in a drug repository program, pursuant to sections 3715.87 to 3715.873 of the Revised Code, if all of the following requirements are met:

(A) Must be licensed as a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code.

(B) Must comply with all applicable federal and state laws, rules, and regulations.

(C) A pharmacy, hospital, or nonprofit clinic that operates a drug repository program that receives donations or dispenses medications to the general public shall notify the board, in a manner determined by the board, within thirty days of establishing a repository program.

(D) A pharmacy, hospital, or nonprofit clinic that no longer operates a drug repository program that receives donations or dispenses medications to the general public shall notify the board, in a manner determined by the board, within thirty days of discontinuation.

Rule 4729:5-10-03 | Donating drugs. (NO CHANGE)

(A) The following may donate or facilitate the donation of a drug, pursuant to the eligibility requirements of rule 4729:5-10-04 of the Administrative Code, to a pharmacy, hospital, or nonprofit clinic that elects to participate in a drug repository program:

(1) Any pharmacy, drug manufacturer, or health care facility, or other person or government entity may donate or give drugs to a drug repository program.

(2) Any person or government entity may facilitate the donation or gift of drugs to the program.

(B) Except as provided in paragraph (C) of this rule, a person electing to donate an eligible dangerous drug shall not have taken custody of the drug prior to the donation. The person may direct the donation through any entity or person authorized in paragraph (A) of this rule.

(C) The restriction in paragraph (B) of this rule does not apply to the following:

(1) Orally administered cancer drugs described in paragraph (B) of rule 4729:5-10-04 of the Administrative Code;

(2) Drugs described in paragraph (C) of rule 4729:5-10-04 of the Administrative Code donated to a charitable pharmacy, hospital, or nonprofit clinic.

(D) A person who resides in an institutional facility and was legally dispensed a dangerous drug pursuant to a patient-specific order may elect to sign and date a donor form prior to donating a drug, which shall state "from this day forward I wish to donate all my remaining unused drugs that are eligible, pursuant to rule 4729:5-10-04 of the Administrative Code, to a drug repository program."

(E) The following may make the decision to donate an eligible drug on behalf of a patient:

(1) A person designated by durable power of attorney, a guardian, or other individual responsible for the care and well-being of a patient; or

(2) An executor, administrator, or trustee of the estate of a deceased patient.

Rule 4729:5-10-05 | Eligibility requirements to receive drugs. (NO CHANGE)

A pharmacy, hospital, or nonprofit clinic that elects to participate in a drug repository program must determine if a person is eligible to receive drugs. A person must meet the following requirements to become an eligible recipient of drugs from a drug repository program:

(A) Is a resident of Ohio or currently resides in this state; and

(B) Meets any of the following criteria:

(1) Is uninsured or underinsured as defined in rule 4729:5-10-01 of the Administrative Code; or

(2) Meets any other eligibility requirements, as determined by the repository programs eligibility policy.

Rule 4729:5-10-06 | Donor and recipient forms. (NO CHANGE)

(A) Each donor must sign an electronic or physical form stating that the donor is the owner of the drug and intends to voluntarily donate the drug to the drug repository program. The donor form must be completed prior to any donation and include at least the following:

(1) The name of the person that was originally dispensed the drugs or the name of the entity that owns the drugs.

(2) The full name, contact phone, and signature of the donor, which may include any of the following:

(a) The person designated by durable power of attorney, a guardian, an individual responsible for the care and well-being of a patient;

(b) The executor, administrator, or trustee of the estate of a deceased patient;

(c) The responsible person or the responsible person's designee of a terminal distributor of dangerous drugs or a drug distributor;

(d) The licensed prescriber or pharmacist responsible for the oversight of the entity donating the drug.

(3) The address of the donor or the entity donating the drug.

(4) The date the form was signed.

(B) The following donor information must also be documented. This information may be documented on the original signed donor form or on an alternate record created by the repository program. If an alternate record is used, the record must include the name of the donor in addition to the required information in this paragraph.

(1) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#).

(2) The strength of the drug donated.

(3) The quantity of the drug donated.

(4) The date the drug was donated.

(C) Prior to receiving donated drugs from a drug repository program, each recipient must sign an electronic or physical form stating they understand the immunity provisions of the program pursuant to division (B) of section 3715.872 of the Revised Code.

(D) Donor forms shall be maintained for a minimum of three years in a readily retrievable manner by the repository program.

(E) Recipient forms shall be maintained for a minimum of three years in a readily retrievable manner by the repository program.

(F) A prescriber shall document the distribution of a personally furnished donated repository program drug to the prescriber's patient pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code and a pharmacy shall document the dispensing of a donated repository program drug pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code. Such records shall indicate that the drug distributed to a patient was from a repository program. If recipient forms are used with each dispensing or personal furnishing, this information may be documented on the recipient form.

Rule 4729:4-1-03 | Requirements for approved treatment providers. (NO CHANGE)

(A) An approved treatment provider, as defined in rule 4729:4-1-01 of the Administrative Code, shall meet or exceed the following requirements:

(1) Certification, as determined by the board, by the Ohio department of mental health and addiction services pursuant to Chapter 5119. of the Revised Code.

(2) Any other treatment provider approved by the board, to include:

(a) An out-of-state provider, when treatment has already been initiated or completed; or

(b) Any provider not certified in accordance with paragraph (A)(1) of this rule.

(3) Any treatment provider must be approved prior to a licensee or registrant participating in the program, unless the board finds exceptional circumstances exist, in which case the board may approve the treatment provider during or after treatment.

(B) An intervenor associated with an approved treatment provider shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the licensee or registrant is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the licensee or registrant fails to comply within one week to a referral for evaluation, the intervenor must report the name of the individual to the board within one business day.

(C) A treatment assessor associated with an approved treatment provider shall evaluate a licensee or registrant referred to the approved treatment provider to determine if the licensee or registrant has a substance use disorder related impairment.

(1) If such an impairment exists, the approved treatment provider shall formulate the licensee or registrant's individualized treatment plan as defined in rule 4729:4-1-01 of the Administrative Code. The specific requirements shall be determined by an assessment of psychological, physical, developmental, family, social, environmental, recreational, and professional needs. The individualized treatment plan shall be part of a treatment contract which the impaired licensee or registrant must sign. If the impaired licensee or registrant fails to sign the treatment contract and enter treatment within forty-eight hours of the determination that the licensee or registrant needs treatment, the approved treatment provider must report the name of the licensee or registrant to the board within one business day.

(D) The designated person for the approved treatment provider shall:

(1) Establish a system of records that will provide for complete information about an impaired licensee or registrant from intervention through the rehabilitation stage;

(2) Establish treatment contracts meeting the requirements of this division and a system of follow up to determine compliance by the impaired licensee or registrant with the treatment contract;

(3) Ensure the confidentiality of the impaired licensee or registrant, except:

(a) If the licensee or registrant fails to comply within one week to a referral for evaluation;

(b) If the impaired licensee or registrant fails to sign the contract and enter treatment within forty-eight hours of the determination that the licensee or registrant needs treatment;

(c) If the impaired licensee or registrant does not suspend practice on entering treatment;

(d) If the impaired licensee or registrant does not comply with the terms of the treatment contract;

(e) If the impaired licensee or registrant resumes practice before the approved treatment provider or monitoring program has made a clear determination that the licensee or registrant is capable of practicing;

(f) If the impaired licensee or registrant suffers a relapse at any time.

(4) Notify the state board of pharmacy within one business day if the licensee or registrant violates any provision of this rule.

IMPORTANT REMINDER: *These are rules governing treatment providers for pharmacists who are subject to probation. They are not regulations on licensed terminal distributors who provide mental health and substance use disorder treatment.*

Rule 4729:4-1-06 | Requirements for approved monitoring programs. (NO CHANGE)

(A) An approved monitoring program, as defined in rule 4729:4-1-01 of the Administrative Code, must be approved by the state board of pharmacy and shall meet or exceed the following requirements:

(1) Have board approved policies and procedures which shall include, but not be limited to, the following:

(a) The program's standards and procedures for care;

(b) The program's standards and training/approval process for personnel.

(2) Have personnel including, but not limited to, an intervenor and a designated person as defined in rule 4729:4-1-01 of the Administrative Code.

(B) An intervenor associated with an approved monitoring program shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the licensee or registrant is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the licensee or registrant fails to comply within one week to a referral for evaluation, the intervenor must report the name of the licensee or registrant to the board within one business day.

(C) The designated person for the limited approved treatment provider shall:

(1) Ensure confidentiality of the impaired licensee or registrant, except:

(a) If the licensee or registrant fails to comply within one week to a referral for evaluation; or

(b) If the impaired licensee or registrant suffers a relapse at any time during or following rehabilitation.

(2) Notify the state board of pharmacy within one business day if the licensee or registrant violates any portion of this rule.

IMPORTANT REMINDER: *These are rules governing treatment providers for pharmacists who are subject to probation. They are not regulations on licensed terminal distributors who provide mental health and substance use disorder treatment.*

Rule 4729:5-8-01 | Definitions. (NO CHANGE)

As used in Chapter 4729:5-8 of the Administrative Code:

(A) "Nonresident terminal distributor of dangerous drugs" or "nonresident terminal distributor" means any person located outside of Ohio that ships, mails, or delivers in any manner, dangerous drugs at retail into Ohio. A nonresident terminal distributor of dangerous drugs shall maintain a license in accordance with sections 4729.54 and 4729.55 of the Revised Code and shall comply with all requirements set forth in this chapter. A nonresident terminal distributor does not include a person shipping drugs into this state for destruction or disposal by an Ohio licensed reverse distributor.

(B) "Dangerous drug" has the same meaning as defined in section 4729.01 of the Revised Code.

(C) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs in the state where the individual is practicing.

(D) "Pharmacist," as used in division (B) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice pharmacy in the state where the individual is practicing.

(E) "Pharmacy" has the same meaning as defined in section 4729.01 of the Revised Code.

(F) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for 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.

Rule 4729:5-8-02 | Licensure. (NO CHANGE)

(A) A person seeking a license as a nonresident terminal distributor of dangerous drugs shall submit an application to the state board of pharmacy that includes all of the following:

(1) Information necessary to demonstrate the qualifications for licensure set forth in section 4729.55 of the Revised Code.

(2) If the applicant's facility maintains a current license in the state where it is located, all the following:

(a) Certification from the appropriate state licensing agency that the applicant maintains at all times a valid, unexpired license, permit, or registration authorizing the possession and sale of dangerous drugs in the state in which the facility is located and from where dangerous drugs are being sold at retail to residents in Ohio. The certification(s) shall include licenses, permits, or registrations required to cover the categories of dangerous drugs which the nonresident terminal distributor of dangerous drugs will be selling at retail to persons in the state of Ohio.

(b) A copy of the most recent inspection report, any warning notices, notice of deficiency reports, or any other related reports issued by a state licensing agency and drug law enforcement agencies of the state in which it is located or any federal agencies regulating and enforcing laws governing the legal distribution of drugs.

(3) Any other information as determined by the board.

(B) A nonresident terminal distributor shall have a responsible person that complies with the requirements of rule 4729:5-2-01 of the Administrative Code.

Rule 4729:10-1-02 | Authorized collectors. (NO CHANGE)

(A) An authorized collector may operate a drug collection receptacle if they meet the requirements specified in 21 CFR Part 1300, 21 CFR Part 1301, 21 CFR Part 1304, 21 CFR Part 1305, 21 CFR Part 1307 and 21 CFR Part 1317 (4/1/2018).

(B) If an authorized collector operates a drug collection receptacle for the collection of non-controlled substances only, the collector shall meet all of the requirements specified in paragraph (A) of this rule.

(C) A long-term care facility may dispose of prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications on behalf of an ultimate user who resides, or has resided, at that long-term care facility pursuant to 21 CFR 1317.80 (4/1/2018).

(D) An authorized collector may operate a mail-back program if they meet the requirements specified in 21 CFR Part 1300, 21 CFR Part 1301, 21 CFR Part 1304, 21 CFR Part 1305, 21 CFR Part 1307 and 21 CFR Part 1317 (4/1/2018).

(E) If an authorized collector operates a mail-back program for the collection of non-controlled substances only, the collector shall meet all of the requirements specified in paragraph (D) of this rule.

(F) An authorized collector shall indicate on a drug collection receptacle or with written materials accompanying a mail-back package that the collection of any of the following is prohibited:

(1) Medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers); and

(2) Schedule I controlled substances.

(G) An authorized collector shall not dispose of the collector's inventory or stock of controlled substances, dangerous drugs or over-the-counter medications in a drug collection receptacle or through a mail-back program.

(H) An authorized collector shall maintain the confidentiality of the ultimate user pursuant to all applicable state and federal laws, rules, and regulations.

(I) An authorized collector shall not operate a take-back event as defined in rule 4729:10-1-01 of the Administrative Code.

Rule 4729:5-17-01 | Medical Oxygen, Nitrous Oxide, Medical Gases and Dialysis Solutions - Definitions. (NO CHANGE)

As used in Chapter 4729:5-17 of the Administrative Code:

(A) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule 4729:5-1-02 of the Administrative Code but shall be limited to a prescriber practicing within the prescriber's applicable scope of practice.

(B) "Medical oxygen" means oxygen that meets the definition of a dangerous drug pursuant to section 4729.01 of the Revised Code.

(C) "Peritoneal dialysis solution" or "dialysis solution" means a commercially manufactured, unopened, sterile dangerous drug solution that is intended to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis.

(D) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

(E) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the supervision and control of dangerous drugs and medical gases 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 medical gases, and maintaining all drug records otherwise required.

(F) "Tamper-evident" means a package, storage container or other physical barrier is sealed or secured in such a way that access to medical gases or dangerous drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

(G) The provisions of this chapter do not apply to a person or facility licensed as a terminal distributor of dangerous drugs that is specifically defined and required to comply with another chapter of this division (EMS organization, veterinary clinic, prescriber clinic, pain management clinic, animal shelter, etc.).

Rule 4729:5-17-02 | Medical Oxygen - General Provisions. (NO CHANGE)

(A) Except as provided in paragraph (H) of this rule, each person, whether located within or outside of this state, who conducts retail sales of medical oxygen in this state shall obtain a limited category II terminal distributor of dangerous drugs license. The requirements of this paragraph do not apply to persons currently licensed to purchase, possess, and sell dangerous drugs at retail in accordance with division 4729:5 of the Administrative Code.

(B) All areas where medical oxygen is stored shall be maintained in a clean and orderly condition. Storage areas shall be maintained at conditions and temperatures which will ensure the integrity of the medical oxygen prior to use as stipulated by the manufacturer's or distributor's labeling.

(C) Medical oxygen shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All retail sellers of medical oxygen shall maintain records of the purchase of oxygen at wholesale and the sale of oxygen at retail, including prescriber orders, for three years at the licensed location. All records shall be readily retrievable.

(1) 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.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(E) A terminal distributor of dangerous drugs shall report the theft or significant loss of medical oxygen pursuant to rule 4729:5-3-02 of the Administrative Code.

(F) Except as provided in paragraphs (G) and (H) of this rule, prior to making an initial sale of medical oxygen to a patient, a terminal distributor of dangerous drugs must have an order issued by a prescriber.

(1) The order must include the full name and address of the patient, the signature of the prescriber, the manually printed, typewritten, electronically generated or preprinted full name and address of the prescriber, the telephone number where the prescriber can be personally contacted during normal business hours, the date of issuance, and documentation of need. A terminal distributor may add the patient's address, prescriber's address, and prescriber's phone number to the order if incomplete on the original order.

(2) The prescriber's order may be transmitted electronically to the retail seller.

(3) All orders issued in accordance with this paragraph are valid for a period of one year from the date of issuance.

(G) S.C.U.B.A. divers who hold a valid certificate in the following nationally recognized S.C.U.B.A. diving certifying organization programs may purchase, possess, and use medical oxygen for the purpose of emergency care or treatment at the scene of a diving emergency pursuant to section 4729.541 of the Revised Code:

(1) Diver alert network (DAN): oxygen first aid for scuba diving injuries;

(2) International association of nitrox and technical divers: oxygen provider course;

(3) Professional association of diving instructors (PADI): emergency first response;

(4) PADI: PADI oxygen first aid;

(5) PADI: rescue diver course;

(6) PADI: tec deep diver;

(7) Scuba schools international: medic first aid emergency oxygen administration;

(8) Technical diving international-S.C.U.B.A. diving international: diver advanced development program as a CPROX administrator;

(9) YMCA: slam rescue;

(10) National association of underwater instructors (NAUI) first aid;

(11) NAUI rescue scuba diver;

(12) NAUI advanced rescue scuba diver;

(13) NAUI first aid instructor;

(14) NAUI oxygen administration;

(15) NAUI instructor; and

(16) Any other program as approved by the board.

(H)

(1) In accordance with policy guidance issued by the United States food and drug administration, oxygen equipment intended for emergency use may be sold without a prescription.

(a) Such equipment shall deliver a minimum flow rate of six liters of oxygen per minute for a minimum of fifteen minutes.

(b) Labeling for emergency oxygen shall not contain references to heart attacks, strokes, shock or any other medical condition amenable to diagnosis or treatment only by a licensed health care professional.

(c) Oxygen units delivering a minimum flow rate of less than six liters of oxygen per minute for a period less than fifteen minutes and labeled for emergency use are considered adulterated and misbranded.

(d) If the units are not intended for emergency use and provide less than six liters of oxygen per minute or are labeled for human use for other than emergency use, such units are regarded as a dangerous drug and shall bear the prescription legend.

(e) The units shall contain no more than eighty minutes (four hundred eighty liters) of USP oxygen.

(2) Persons that only sell oxygen equipment intended for emergency use that meet the criteria listed in paragraph (H)(1) of this rule shall not be required to obtain licensure as a terminal distributor of dangerous drugs in accordance with paragraph (A) of this rule.

(3) Persons that possess and administer oxygen equipment intended for emergency use that meet the criteria listed in paragraph (H)(1) of this rule shall not be required to obtain licensure as a terminal distributor of dangerous drugs.

Rule 4729:5-17-03 | Nitrous Oxide - General Provisions. (NO CHANGE)

(A) Each person located within this state who seeks to purchase and possess nitrous oxide for the purpose of using it as a direct ingredient in food pursuant to Title 21 CFR 184.1545 (04/1/2018) shall obtain a limited category II terminal distributor of dangerous drugs license.

(B) All areas where nitrous oxide is stored shall be maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the nitrous oxide prior to use as stipulated by the manufacturer's or distributor's labeling.

(C) Nitrous oxide shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All food processors and retail sellers of food licensed in accordance with this rule shall maintain records of purchase at wholesale and use in the processing food for three years at the licensed location. All records shall be readily retrievable.

(1) 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.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(E) A terminal distributor of dangerous drugs shall report the theft or significant loss of nitrous oxide pursuant to rule 4729:5-3-02 of the Administrative Code.

Rule 4729:5-17-04 | Compressed Medical Gasses - General Provisions and Safety Program. (NO CHANGE)

(A) Each person, whether located within or outside this state, who seeks to possess or sell compressed medical gases in this state shall maintain, based upon the person's business activities, a wholesale distributor of dangerous drugs license in accordance with section 4729.52 of the Revised Code or terminal distributor of dangerous drugs license in accordance with section 4729.54 of the Revised Code.

(B) Wholesale or terminal distributors of dangerous drugs who fill containers with compressed medical gases must comply with the current good manufacturing practice regulations issued pursuant to the Federal Food, Drug and Cosmetic Act (4/1/2018) and the current regulations and guidelines issued pursuant to Title 21 CFR 10.90 (4/1/2018).

(C) Records required by state and federal laws, rules, and regulations governing the sale of dangerous drugs and the filling of containers with compressed medical gases shall be maintained for a period of three years at the licensed location. All records shall be readily retrievable.

(1) A wholesale or terminal distributor of dangerous drugs 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.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the wholesale or terminal distributor of dangerous drugs.

(D) A terminal distributor of dangerous drugs shall report the theft or significant loss of compressed medical gasses pursuant to rule 4729:5-3-02 of the Administrative Code.

(E) A wholesale distributor of dangerous drugs shall report the theft or significant loss of compressed medical gasses pursuant to rule 4729:6-3-02 of the Administrative Code.

(F) A medical gases safety program developed pursuant to section 4729.70 of the Revised Code shall comply with the following requirements:

(1) The instructors shall have the appropriate education and experience to teach a program in medical gas safety.

(2) The program shall be presented to all individuals who fill, install, connect, or disconnect medical gases contained in cryogenic vessels that are portable and intended for use in administering direct treatment to one or more individuals.

(3) Successful participation and demonstrated competency in a program must be completed prior to an individual filling, installing, connecting, or disconnecting a medical gas contained within a cryogenic vessel.

(4) The program must include the following:

(a) The description of a cryogenic vessel, including:

(i) Valve inlet and outlet connections;

(ii) Safety systems associated with each outlet;

(iii) Proper labeling;

(iv) Color coding; and

(v) Gas identification.

(b) A review of each medical gas listed in division (C)(2) of section 4729.70 of the Revised Code that may be contained in a cryogenic vessel, including:

(i) A description of the properties of the gas or liquid;

(ii) The precautions and warnings associated with the gas or liquid;

(iii) Procedures for handling exposure to the gas or liquid; and

(iv) Procedures to handling the gas or liquid during an emergency.

(c) The proper installation of cryogenic vessels, including the following:

(i) Connecting and disconnecting supply lines;

(ii) Recognizing silver-brazed fittings or other acceptable mechanical means that make the connection a permanent and integral part of the valve;

(iii) Recognizing that changing or adapting the fittings for another gas service is strictly prohibited except in accordance paragraph (H) of this rule;

(iv) Recognizing the appropriate devices through which medical gases are delivered from cryogenic vessels;

(v) Detecting and reporting leaks;

(vi) Transporting cryogenic vessels appropriately within a facility; and

(vii) Appropriate storage of cryogenic vessels.

(5) The program instructor must document the participation of an individual in a medical gases safety program. The documentation must be maintained by the individual's employer for a period of at least three years and made readily retrievable.

(6) Individuals who install, connect, or disconnect medical gases from cryogenic vessels must attend a medical gases safety program at least once every two years.

(G) No person shall modify a cryogenic vessel, connection, or valve or adapt a connection for another gas service pursuant to division (D) of section 4729.70 of the Revised Code.

(H) Paragraph (G) of this rule does not apply to an employee or agent of a firm owning the cryogenic vessel and who is charged with the responsibility of conducting applicable vessel maintenance, changing service from one medical gas to another, or bringing a vessel into compliance with section 4729.70 of the Revised Code.

(1) Such employee or agent shall meet the following requirements:

(a) Successful completion of a medical gases safety program pursuant to paragraph (F) of this rule.

(b) Successful participation and demonstrated competency in a cryogenic vessel modification program administered by an instructor with the appropriate education and experience. The program must be based on written and validated procedures. The employee or agent must participate in the program annually and the program shall include the following:

(i) Removing, adding, or adapting cryogenic vessel connections and valves;

(ii) Modifying cryogenic vessels;

(iii) Conducting cryogenic vessel maintenance;

(iv) Changing the cryogenic vessel from one medical gas to another;

(v) Bringing a cryogenic vessel into compliance with section 4729.70 of the Revised Code;

(vi) Silver brazing or welding techniques and certification of the individual if applicable; and

(vii) Removing and adding suitable mechanical means to make a connection a permanent and integral part of the valve.

(2) An employer must document the successful participation and demonstrated competency of an employee or agent in a cryogenic vessel modification program. The documentation must be maintained by the employer for a period of at least three years and made available, upon request, to those business entities receiving service and to the state board of pharmacy.

Rule 4729:5-17-05 | Dialysis Solutions - General Provisions.

(A) Each person, whether located within or outside this state, who sells peritoneal dialysis solutions in this state shall obtain a limited category II terminal distributor of dangerous drugs license. The requirements of this paragraph do not apply to persons currently licensed to purchase, possess, and sell dangerous drugs at retail in ~~**accordnce**~~ **accordance** with **division** ~~**divison**~~ 4729:5 of the Administrative Code.

(B) All areas where dialysis solution is 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 dialysis solution prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(C) Dialysis solutions shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All retail sellers of peritoneal dialysis solutions shall maintain records of purchase of dialysis solutions at wholesale and sale of dialysis solutions at retail for three years at the licensed location. All records shall be readily retrievable.

(1) 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.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(E) Prior to making an initial sale of dialysis solutions to a patient, a terminal distributor of dangerous drugs must have an order issued by a prescriber.

(1) The order must include the full name and address of the patient, the signature of the prescriber, the manually printed, typewritten, electronically generated or preprinted full name and address of the prescriber, the telephone number where the prescriber can be personally contacted during normal business hours, the date of issuance and the complete and accurate identification of each such product to be provided to the patient.

(2) The prescriber's order may be transmitted electronically to the retail seller.

(3) All orders issued in accordance with this paragraph are valid for a period of one year from the date of issuance.

(F) A terminal distributor of dangerous drugs shall report the theft or significant loss of dialysis solution pursuant to rule 4729:5-3-02 of the Administrative Code.

Rule 4729:3-5-03 | Veteran and military family provisions related to continuing education. (AMEND)

(A) Extension of continuing education requirements.

(1) In accordance with section 5903.12 of the Revised Code, the state board of pharmacy shall grant extension periods and waivers for the completion of continuing education requirements for active duty veteran members and the spouses of active duty veterans. If a registered pharmacy technician or their spouse is called to active duty for military service, the time period allowed for completion of any continuing education requirements will be extended by the amount of time that the technician or the technician's spouse was on active duty.

(2) Upon receiving the application and proper documentation, the board's **~~director of licensing~~** **executive director or director's designee** shall extend the continuing education reporting period by an amount of time equal to the total number of months that the registrant or their spouse spent on active duty during the current reporting period. For purposes of this division, any portion of a month served on active duty shall be considered one full month.

(3) The registrant shall submit proper documentation certifying the active duty service and the length of that active duty service. Documentation required to obtain an extension or waiver pursuant to paragraph (A)(1) of this rule will be published on the state board of pharmacy's website: www.pharmacy.ohio.gov.

(B) Determining fulfillment of continuing education.

(1) If a registered pharmacy technician is a veteran, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the registration holder no more than two years prior to the thirty first of march of the year in which a technician's registration must be renewed when determining the fulfillment of any continuing education requirements.

(2) For the board to consider relevant education, training, or service completed by a registered technician, the registrant shall submit a request for consideration and evidence or documentation of the education, training, or service to the **~~director of licensing~~** **executive director or director's designee** at least thirty days prior to the required continuing education reporting period pursuant to rule 4729:3-5-02 of the Administrative Code.

Rule 4729:5-2-06 | Zoning Requirements for Terminal Distributors of Dangerous Drugs. (NEW)

(A) This rule does not apply to the following:

(1) A veterinarian or veterinary clinic as defined in Chapter 4729:5-20 of the Administrative Code;

(2) A dentist providing anesthesia services to treat current or prospective patients outside of the location licensed as a terminal distributor of dangerous drugs; or

(3) Any other business type as determined by the board.

(B) Except as provided in paragraph (C) of this rule, a terminal distributor of dangerous drugs shall not operate out of a location that is zoned for residential use and/or is a residence or personal dwelling.

(C) A terminal distributor of dangerous drugs may operate in a location that is a residence or personal dwelling if it meets all the following conditions:

(1) Drugs and record storage areas are maintained in either:

(a) A structure or building that is detached or separate from the residence or personal dwelling; or

(b) There is clear delineation between the licensed location and the residence or personal dwelling where the licensed location has a separate means of egress and is physically secure from the rest of the residence.

(2) A terminal distributor license shall only be issued if the location is owned by a prescriber or pharmacist.

(3) The licensed location shall be in compliance with applicable building, fire, safety, and zoning statutes, local ordinances, and rules and regulations adopted by the locality in which the licensee’s property is located.

(4) The licensed location shall be able to demonstrate compliance with this rule and all other requirements pursuant to Chapter 4729. of the Revised Code and all rules adopted thereunder.

(D) Locations licensed as a terminal distributor of dangerous drugs on or before the effective date of this rule shall have until March 31, 2027, to comply with the requirements of this rule.

(E) Licensees that submit a change of business description in accordance with rule 4729:5-2-03 of the Administrative Code shall comply with the requirements of this rule.

Rule 4729:8-3-03 | Electronic format required for the transmission of drug sales. (RESCIND CURRENT / NEW)

(A) All prescription dispensing information or prescriber personally furnishing information required to be submitted to the board pursuant to rule 4729-8-3-02 of the Administrative Code must be transmitted in the following format specified by the "American Society for Automation in Pharmacy" (ASAP) for prescription monitoring programs:

(1) ASAP Version 5.0 Standard for Prescription Drug Monitoring Programs (1/1/2024); or

(2) Until May 1, 2025, ASAP Version 4.2A Standard for Prescription Drug Monitoring Programs (3/15/2017).

(B) The board's executive director or the director's designee may authorize up to a six-month extension to the implementation of ASAP Version 5.0 beyond April 1, 2025. Such extensions may only be considered if the pharmacy or prescriber has made all reasonable and prudent attempts to meet the deadline.

(C) In the event that a pharmacy or a prescriber cannot electronically transmit the required information pursuant to paragraph (A) of this rule, the pharmacy or prescriber may request a variance from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable format.

(D) All wholesale data required to be submitted to the board of pharmacy pursuant to rule 4729-8-3-02 of the Administrative Code shall be transmitted in the report format used when transmitting controlled substance data to the federal drug enforcement administration via the "Automation of Reports and Consolidated Orders System (ARCOS)" or other mutually acceptable format.

(E) In the event that a drug distributor or terminal distributor cannot electronically transmit the required information pursuant to paragraph (D) of this rule, the drug distributor or terminal distributor may request a variance from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable format.

Rule 4729:8-1-01 | Ohio Automated Rx Reporting System - Definitions. (AMEND)

As used in division 4729:8 of the Administrative Code:

(A) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(B) "Central fill pharmacy" has the same meaning as in rule 4729:5-5-19 of the Administrative Code.

(~~B~~ **C**) "Distributor of dangerous drugs" or "drug distributor" means the following persons licensed in accordance with section 4729.52 of the Revised Code and division 4729:6 of the Administrative Code:

(1) Wholesale distributors of dangerous drugs, including virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(D) "Designated representative" means the dispensary key employee responsible for acting in compliance with agency 3796 of the Administrative Code.

(E) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

(F) "Dispensary" means a holder of a valid retail dispensary license in accordance with Chapter 3796. of the Revised Code.

(G) "Originating pharmacy" has the same meaning as in rule 4729:5-5-19 of the Administrative Code.

(H) "Opioid treatment program" has the same meaning as in Chapter 4729:5-21 of the Administrative Code.

(~~C~~ **H**) "Outpatient" means any person who receives drugs for use outside of an institutional facility as defined in agency 4729 of the Administrative Code.

(~~D~~ **G**) "Peer review committee" has the same meaning as in section 2305.25 of the Revised Code, except that it includes only a peer review committee of a hospital or a peer review committee of a nonprofit health care corporation that is a member of the hospital or of which the hospital is a member.

(~~E~~ **H**) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

(~~F~~ **I**) "Pharmacy" has the same meaning as in section 4729.01 of the Revised Code.

(~~G~~ **J**) "Prescriber" or "licensed health professional authorized to prescribe drugs" have the same meaning as in section 4729.01 of the Revised Code.

(~~H~~ **K**) "Terminal distributor of dangerous drugs" or "terminal distributor" has the same meaning as in section 4729.01 of the Revised Code.

(~~I~~ **L**) "Sale" and "sell" has the same meaning as in section 4729.01 of the Revised Code.

(~~J~~ **M**) "Wholesale sale" and "sale at wholesale" have the same meaning as in section 4729.01 of the Revised Code. Wholesale sale also includes the following:

(1) An occasional sale conducted in accordance with section 4729.51 of the Revised Code;

(2) The sale of a sample or complimentary supply, as defined in rule 4729:6-3-08 of the Administrative Code, to a prescriber or terminal distributor;

(3) The transfer or sale of a non-patient specific dangerous drug to a prescriber or terminal distributor.

~~**(K) "Zero report" means a report documenting that none of the drugs listed in Chapter 4729:8-2 of the Administrative code were sold, dispensed or personally furnished during the required reporting period.**~~

(N) "Zero report" means either:

(1) A report documenting that none of the drugs listed in Chapter 4729:8-2 of the Administrative Code were sold, dispensed or personally furnished during the required reporting period; or

(2) For a dispensary, a report documenting that no medical marijuana was sold or dispensed.

Rule 4729:8-2-01 | List of drugs to be reported. (NO CHANGE)

Pursuant to section 4729.75 of the Revised Code, the required information for the following drugs pursuant to an outpatient prescription, personally furnished by a prescriber, or sold at wholesale to a terminal distributor of dangerous drugs shall be submitted to the state board of pharmacy pursuant to sections 4729.77, 4729.78 and 4729.79 of the Revised Code and this division of the Administrative Code:

(A) All schedule II controlled substances;

(B) All schedule III controlled substances;

(C) All schedule IV controlled substances;

(D) All schedule V controlled substances.

Rule 4729:8-2-02 | Additional drugs to be reported. (NO CHANGE)

(A) Pursuant to section 4729.75 of the Revised Code, the required information for the following drugs pursuant to an outpatient prescription, personally furnished by a prescriber, or sold at wholesale to a prescriber or terminal distributor of dangerous drugs shall be submitted to the state board of pharmacy in accordance with sections 4729.77, 4729.78 and 4729.79 of the Revised Code and this division of the Administrative Code:

All dangerous drug products containing gabapentin.

(B) Pursuant to section 4729.75 of the Revised Code, the required information for the following drugs pursuant to an outpatient prescription shall be submitted to the state board of pharmacy in accordance with section 4729.77 of the Revised Code and this division of the Administrative Code:

All dangerous drug products containing naltrexone that are indicated for the treatment of alcohol dependence or the prevention of relapse to opioid dependence.

Rule 4729:8-3-01 | Entities required to submit information. (AMEND)

The following entities are required to submit the specified dispensing, personal furnishing, or wholesale sale information in accordance with this chapter of the Administrative Code to the state board of pharmacy for the operation of the drug database:

(A) All pharmacies located within this state and licensed as a terminal distributor of dangerous drugs shall report all drugs listed in Chapter 4729:8-2 of the Administrative Code that are dispensed to outpatients.

(B) All pharmacies located outside this state and licensed as a terminal distributor of dangerous drugs shall report all drugs listed in Chapter 4729:8-2 of the Administrative Code that are dispensed to outpatients residing in this state.

(C) Except as provided in rule 4729:8-2-02 of the Administrative Code, all licensed drug distributors and terminal distributors of dangerous drugs located within this state that sell at wholesale drugs listed in Chapter 4729:8-2 of the Administrative Code to prescribers or terminal distributors of dangerous drugs shall report those drug transactions in accordance with the wholesale reporting requirements of this chapter.

(D) Except as provided in rule 4729:8-2-02 of the Administrative Code, all licensed drug distributors and terminal distributors of dangerous drugs located outside this state that sell at wholesale drugs listed in Chapter 4729:8-2 of the Administrative Code to prescribers or terminal distributors of dangerous drugs located within this state shall report those drug transactions in accordance with the wholesale reporting requirements of this chapter.

(E) Except as provided in rule 4729:8-2-02 of the Administrative Code, all prescribers, except veterinarians, located within this state shall report all drugs listed in Chapter 4729:8-2 of the Administrative Code that are personally furnished to patients.

(F) A retail dispensary licensed under Chapter 3796. of the Revised Code in accordance with section 4729.771 of the Revised Code.

(G) An opioid treatment program licensed as a terminal distributor of dangerous drugs is exempted from the reporting requirements of this division.

(1) An opioid treatment program shall report patient information via the central registry established in rule 5122-40-08 of the Administrative Code.

(2) Reporting of patient information pursuant to paragraph (G)(1) of this rule shall be made in compliance with 42 CFR Part 2.

Rule 4729:8-3-02 | Information required for submission. (AMEND)

(A) Pharmacies pursuant to paragraphs (A) and (B) of rule 4729:8-3-01 of the Administrative Code that dispense drugs listed in Chapter 4729:8-2 of the Administrative Code to outpatients shall report the following dispensing information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Pharmacy drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Pharmacy name;

(3) Pharmacy address;

(4) Pharmacy telephone number;

(5) Pharmacy dispensing software vendor;

(6) Pharmacy license number, if both the drug enforcement administration registration and national provider identifier are not provided;

(7) Type of pharmacy or dispenser;

(8) Indication if entity is a mail order pharmacy;

(~~5~~ **9**) Patient full name;

(~~6~~ **10**) Patient residential address;

(~~7~~ **11**) Patient telephone number;

(~~8~~ **12**) Patient date of birth;

(~~9~~ **13**) Patient gender;

(14) Species code;

(15) Owner's name for veterinary patients;

(16) Owner's date of birth for veterinary patients;

(17) Owner's gender for veterinary patients;

(18) Name of animal;

(19) Veterinary species code for veterinary patients that is either:

(a) For small animals: 03;

(b) For large animals, including livestock: 06.

(~~10~~ **20**) Prescriber's full name (first name and last name);

(21) Transmission form of prescription (e.g., written, verbal, electronic, etc.);

(~~11~~ **22**) Prescriber's drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(~~12~~ **23**) Date prescription was issued by the prescriber;

(~~13~~ **24**) Date the prescription was dispensed ~~**or sold**~~ by the pharmacy;

(25) Date the prescription was sold by the pharmacy, which shall be the date the prescription is sold, picked up, or otherwise left the pharmacy;

(~~14~~ **26**) Indication of whether the prescription dispensed is new or a refill;

(~~15~~ **27**) Number of the refill being dispensed;

(~~16~~ **28**) National drug code of the drug dispensed;

(29) Indication if the product is compounded in accordance with division 4729:7 of the Administrative Code;

(~~17~~ **30**) Quantity of the drug prescribed;

(~~18~~ **31**) Quantity of drug dispensed;

(~~19~~ **32**) Number of days' supply of the drug dispensed as indicated by the prescriber pursuant to agency 4729 of the Administrative Code, except as follows:

(a) If a days' supply is not indicated by the prescriber, the pharmacy shall calculate and report the number of days' supply of the drug dispensed;

(b) If the quantity of drug dispensed is different from the quantity indicated on the prescription, the pharmacy shall calculate and report the number of days' supply of the drug dispensed.

(~~20~~ **33**) Serial or prescription number assigned to the prescription order;

(~~21~~ **34**) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation. Use of discount cards shall be reported as private pay;

(~~22~~ **35**) Pharmacy national provider identification (NPI) number;

(~~23~~ **36**) Prescriber's national provider identification (NPI) number, if prescriber does not have an NPI**, then the prescriber's state license number or** another mutually acceptable identifier;

(37) Pharmacist national provider identifier (NPI).

(a) If a pharmacist other than the dispensing pharmacist conducted the drug utilization review per rule 4729:5-5-08 of the Administrative Code, report the NPI of the pharmacist who conducted the drug utilization review;

(b) If a pharmacist does not have an NPI, report the pharmacist's license number or another mutually acceptable identifier;

(38) Name of pharmacist. If a pharmacist other than the dispensing pharmacist conducted the drug utilization review per rule 4729:5-5-08 of the Administrative Code, report the full name of the pharmacist who conducted the drug utilization review;

(~~24~~ **39**) Any of the following as indicated by the prescriber pursuant to agency 4729 of the Administrative Code:

(a) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance drug is being used to treat. The code shall, at a minimum, include the first four alpha-numeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5);

(b) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the "Code on Dental Procedures and Nomenclature" (CDT code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription;

(c) If no such code is indicated on the prescription, the pharmacy shall indicate "NC" in the diagnosis data field.

(B) Prescribers pursuant to paragraph (E) of rule 4729:8-3-01 of the Administrative Code that personally furnish drugs listed in Chapter 4729:8-2 of the Administrative Code shall report the following information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Prescriber drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Prescriber full name (first and last name);

(3) Prescriber address;

(4) Prescriber telephone number;

(5) Patient full name;

(6) Patient residential address;

(7) Patient telephone number;

(8) Patient date of birth;

(9) Patient gender;

(10) Date the drug was personally furnished by the prescriber;

(11) National drug code of the drug personally furnished;

(12) Quantity of drug personally furnished;

(13) Number of intended days' supply of drug personally furnished;

(14) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation. Use of discount cards shall be reported as private pay;

(15) Either of the following:

(a) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance drug is being used to treat. The code shall, at a minimum, include the first four alpha numeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5);

(b) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the "Code on Dental Procedures and Nomenclature" (CDT code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription.

(C) Drug distributors and terminal distributors pursuant to paragraphs (C) and (D) of rule 4729:8-3-01 of the Administrative Code that sell at wholesale drugs listed in Chapter 4729:8-2 of the Administrative Code shall report the following information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Drug distributor or terminal distributor drug enforcement administration registration number. If not applicable, then another mutually acceptable identifier;

(2) Purchaser's drug enforcement administration registration number. If not applicable, then another mutually acceptable identifier;

(3) National drug code number of the drug sold;

(4) Quantity of the drug sold;

(5) Date of sale; and

(6) Transaction identifier or invoice number.

(D) Drug distributors shall report suspicious orders and customer information pursuant to rule 4729:6-3-05 of the Administrative Code to the drug database established in section 4729.75 of the Revised Code.

Rule 4729:8-3-02.1 | Supplemental information required for submission. (NEW)

(A) Pharmacies pursuant to paragraphs (A) and (B) of rule 4729:8-3-01 of the Administrative Code that dispense drugs listed in Chapter 4729:8-2 of the Administrative Code to outpatients shall report the following supplemental dispensing information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Patient race;

(2) Patient ethnicity; and

(3) Last four digits of patient social security number.

(B) Prescribers pursuant to paragraph (E) of rule 4729:8-3-01 of the Administrative Code that personally furnish drugs listed in Chapter 4729:8-2 of the Administrative Code shall report the following supplemental information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Patient race;

(2) Patient ethnicity; and

(3) Last four digits of patient social security number.

Rule 4729:8-3-04 | Frequency requirements for submitting drug database information. (AMEND)

(A) A terminal distributor or prescriber that has been in possession of a drug listed in Chapter 4729:8-2 of the Administrative Code for dispensing or personally furnishing within the previous three years shall submit to the board of pharmacy, at least daily, either of the following:

(1) All information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code.

(2) A zero report, if a terminal distributor has no drug dispensing information or a prescriber has no personally furnishing information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code.

(B) The information required to be reported pursuant to paragraph (A) of this rule shall be consecutive and inclusive from the last date and time the information was submitted to the board of pharmacy and shall be reported no later than thirty-six hours after the last time reported.

(C) Any record of a dispensed or personally furnished drug listed in Chapter 4729:8-2 of the Administrative Code shall be reported to the board of pharmacy within twenty-four hours of being dispensed or personally furnished.

(D) Any terminal distributor or prescriber whose normal business hours are not seven days per week shall electronically indicate their normal business hours to the board and no zero report will be required for the terminal distributor or prescriber's non-business days.

(E) If a terminal distributor or prescriber ceases to dispense or personally furnish a drug listed in Chapter 4729:8-2 of the Administrative Code, the responsible person on the terminal distributor of dangerous drugs license or the prescriber shall notify the board of pharmacy in writing and request an exemption to reporting.

If at any time a terminal distributor or prescriber begins dispensing or personally furnishing drugs listed in Chapter 4729:8-2 of the Administrative Code, the exemption to reporting shall no longer be valid and the terminal distributor or prescriber shall start reporting in accordance with this rule.

(F) A drug distributor that has been in possession of a drug listed in Chapter 4729:8-2 of the Administrative Code for sale at wholesale within the previous three years shall submit to the board of pharmacy, at least monthly, either of the following:

(1) All information required to be submitted to the board pursuant to this division of the Administrative Code.

(2) A zero report, if a drug distributor has no drug sale information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code.

(G) All wholesale sale information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code shall be submitted at least monthly. The information shall be consecutive and inclusive from the last date and time the information was submitted and shall be reported no later than forty-five days after the date of the wholesale sale.

(H) If a drug distributor, prescriber, or terminal distributor cannot submit the required information at the required intervals specified in this rule, the drug distributor, terminal distributor or prescriber may request an extension from the **board's** ~~**boards**~~ executive director or the ~~**directors**~~ **director's** designee to submit the required information in a mutually acceptable time frame.

Rule 4729:8-3-05 | Corrections to the drug database. (AMEND)

(A) All information required to be submitted in accordance with this division shall be submitted to the drug database in an accurate and timely manner.

(B) If the omission of drug sale information is discovered, the omitted information shall be submitted to the board of pharmacy by the terminal distributor, prescriber, or drug distributor during the next reporting time period after the discovery.

(C) If erroneous drug sale information is discovered, the terminal distributor, drug distributor or prescriber shall notify the board of pharmacy within twenty-four hours of the discovery. The corrected information must be submitted to the board of pharmacy by the terminal distributor, prescriber**,** or drug distributor within seven days of the discovery.

(D) If the omission of data or erroneous data is the result of a computer programming error, the terminal distributor, prescriber, or drug distributor must notify the board of pharmacy immediately by telephone and submit written or electronic documentation. The documentation shall fully describe the error and propose a mutually agreed upon date for submitting the corrected information.

(E) Except as noted in paragraph (D) of this rule, all data must be submitted or corrected electronically unless prior permission for an alternate method is granted by the **board's** ~~**boards**~~ executive director or the ~~**directors**~~ **director's** designee.

(F) If utilizing a central fill pharmacy to report to the drug database in accordance with this division of the Administrative Code, the central fill pharmacy and the originating pharmacy shall implement a process to submit a correction if the drug is returned to stock pursuant to rule 4729:5-5-22 of the Administrative Code. It shall be the responsibility of the reporting pharmacy to ensure this process is completed in accordance with this rule.

Rule 4729:8-4-01 | Procedures for obtaining drug database information and access by peer review committees. (AMEND)

(A) Persons that are permitted pursuant to section 4729.80 of the Revised Code to obtain information from the drug database shall comply with all application procedures, requirements and acceptable use policies adopted by the board.

(B) An individual seeking the individual's own database information shall comply with the following:

(1) Complete a notarized request form giving such information as required by the board of pharmacy;

(2) Submit the completed form in person or by mail;

(3) Receive the information in person at the board of pharmacy office during normal business hours and show proof of identity with a current government issued form of identification that contains a picture such as a current state issued identification card, a current state issued driver's license, or a valid passport; and

(4) The person may be required to pay the cost of printing the document as determined by the board of pharmacy's current per page rate.

(C) Pursuant to section 4729.80 of the Revised Code, the board shall provide the following information to a designated representative of a peer review committee relating to a prescriber who is subject to the committee's evaluation, supervision, or discipline:

(1) A summary of the prescriber's prescribing record, if such a record is created by the board;

(2) Information from the database, in a format determined by the board, relating to a current or previous patient of the prescriber who is subject to the **committee's** ~~**committees**~~ evaluation, supervision, or discipline.

Rule 4729:8-4-02 | Extension to the information storage requirements and the provision of database statistics. (NO CHANGE)

(A) A government entity or a law enforcement agency pursuant to section 4729.82 of the Revised Code may request that specific information in the database related to an open investigation be retained beyond the five-year information retention requirement. The government entity or law enforcement agency must submit a written request on a form giving such information as required by the board of pharmacy.

(B) The board of pharmacy may provide or present database statistics and law enforcement outcomes based on request information pursuant to section 4729.80 of the Revised Code. The information shall not identify a person and will be provided as determined by the board of pharmacy in summary, statistical, or aggregate form.

Rule 4729:8-4-03 | Access to opioid treatment program data provided by the Ohio department of mental health and addiction services. (AMEND)

(A) Pursuant to ~~**division (A)(23) of**~~ section 4729.80 of the Revised Code, the following persons shall be permitted to access opioid treatment program data provided by the Ohio department of mental health and addiction services in accordance with section 4729.772 of the Revised Code:

(1) Prescriber and prescriber delegates as authorized in ~~**division (A)(5) of section**~~ **under** 4729.80 of the Revised Code;

(2) Pharmacist and pharmacist delegates as authorized ~~**in division (A)(6) of**~~ **under** section 4729.80 of the Revised Code;

(3) The director of health as authorized ~~**in division (A)(13) of**~~ **under** section 4729.80 of the Revised Code;

(4) An individual listed in paragraphs (A)(1) and (A)(2) of this rule who is from or participating with another state's prescription monitoring program; and

~~**(4) An individual listed in division (A)(5) or (A)(6) of section 4729.80 who is from or participating with another states prescription monitoring program; and**~~

(5) A coroner, deputy coroner, or coroner's delegate as authorized ~~**in division (A)(17) of**~~ **under** section 4729.80 of the Revised Code.

(B) Nothing in this rule shall be construed to limit the state board of ~~**pharmacys**~~ **pharmacy's** access and use of data collected by the drug database to carry out its responsibilities in accordance with section 4729.81 of the Revised Code.

4729:6-3-05 **Suspicious order monitoring and due diligence.**

(A) As used in this rule:

(1) "Customer" means a person located in this state that orders or seeks to order a reported drug from an Ohio licensed drug distributor and includes the following:

(a) A licensed terminal distributor of dangerous drugs; or

(b) A prescriber who possesses, or possesses for sale or sells, at retail, a dangerous drug.

(2) "Prescriber" has the same meaning as in section 4729.01 of the Revised Code.

(3) "Reported drug" means any dangerous drug whose sale is required to be reported to the drug database pursuant to ~~agency 4729~~division 4729:8 of the Administrative Code. A reported drug shall not include any list I or list II chemicals listed in 21 CFR Section 1310.02 (10/31/2023).

(B) This rule only applies to the following drug distributors licensed in accordance with section 4729.52 of the Revised Code:

(1) Wholesale distributors of dangerous drugs;

(2) Virtual wholesalers;

(3) Manufacturers of dangerous drugs; and

(4) Outsourcing facilities.

(C) Drug distributors listed in paragraph (B) of this rule shall design and operate a system to identify and report suspicious orders by customers for reported drugs. Suspicious orders shall include, but are not limited to, the following:

(1) Orders of unusual size;

(2) Orders deviating substantially from a normal pattern; and

(3) Orders of unusual frequency.

(D) Prior to any shipment of an order that a distributor has identified as suspicious, two persons designated by the distributor's responsible person must independently analyze the order. In order to proceed with the shipment and complete the sale, each

of the two ~~persons~~people designated must determine that the order is not likely to be diverted from legitimate channels.

(E) All suspicious orders, regardless of actual sale, shall be submitted electronically in a manner and format determined by the board. The electronic submission of suspicious orders shall include all information as required by the board and shall be submitted within five days of the order being identified as suspicious by the drug distributor.

(F) All drug distributors listed in paragraph (B) of this rule shall submit a zero report, in a manner determined by the board, if no suspicious orders have been identified by the distributor in a calendar month. The zero report shall be submitted within fifteen days of the end of the calendar month.

(G)

(1) Except as provided in paragraph (G)(2) of this rule, a drug distributor listed in paragraph (B) of this rule shall exercise due diligence to identify customers ordering or seeking to order reported drugs to establish the normal and expected transactions conducted by those persons and to identify and prevent the sale of reported drugs that are likely to be diverted from legitimate channels. Such measures shall include, but are not limited to, the following which shall ~~to~~ be conducted prior to an initial sale and on an annual basis:

(a) Questionnaires and affirmative steps by the drug distributor to confirm the accuracy and validity of the information provided.

(b) For a customer who is a prescriber, confirmation of prescriber type (physician, dentist, veterinarian, etc.), specialty practice area (oncology, geriatrics, pain management, etc.) and if the prescriber personally furnishes reported drugs and the quantity personally furnished.

(c) Review of drug utilization reports.

(d) Obtaining and conducting a review of the following information:

(i) The methods of payment accepted (cash, insurance, medicaid, medicare) and in what ratios;

(ii) The ratio of controlled vs. non-controlled drug orders and overall sales;

(iii) Orders for reported drugs from other drug distributors made available by the United States drug enforcement

~~administration's~~administration's automation of reports and consolidated orders system; and

(iv) The proportion of out-of-state patients served compared to in-state patients.

(2) A drug distributor receiving a request for an initial sale for a reported drug may conduct the sale without complying with paragraph (G)(1) of this rule if all the following applies:

(a) The sale is to an institutional facility as defined in ~~agency 4729~~Chapter 4729:5-9 of the Revised Code that is a new customer of the distributor;

(b) The drug distributor documents that the order is to meet an emergent need; and

(c) The drug distributor completes the requirements set forth in paragraph (G)(1) of the rule no later than sixty days from the date of sale.

(H) Any customer that may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels, including those to whom a drug distributor refuses to sell, shall be electronically reported by the drug distributor in a manner and format determined by the board. The electronic submission of such customers shall include all information as required by the board and shall be submitted within five days of refusal, cessation or identification by the drug distributor.

~~(I) Within ninety days of the effective date of this rule, a drug distributor shall provide, in a manner and format determined by the board, information on all customers in this state the distributor has refused to sell to or has stopped selling to within the past three years because the distributor has identified the customer as engaging in possible activities that may cause reported drugs to be diverted from legitimate channels. The submission of information shall contain the customer's name, address, drug enforcement administration registration (if applicable), terminal distributor of dangerous drugs license number (if applicable), and a detailed explanation of why the distributor identified the customer as a possible diversion risk.~~

~~(J)~~(I) All drug distributors described in paragraph (~~A~~B) of this rule shall maintain and implement policies and procedures that include all the following:

(1) The design and operation of a suspicious order monitoring and reporting system.

(2) A system to collect the necessary information on customers in accordance with paragraph (G) of this rule.

(3) Mandatory training, to be conducted annually, for staff responsible for the processing of all orders for reported drugs that includes all the following:

(a) The drug distributor's suspicious order monitoring system;

(b) The process to collect all relevant information on customers in accordance with paragraph (G) of this rule;

(c) The process for submission of suspicious orders and customers who may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels to the board; and

(d) Information on submitting a confidential report of a suspicious order or customer engaging in possible activities that may cause reported drugs to be diverted from legitimate channels by using the board's online electronic complaint form that can accessed by visiting: www.pharmacy.ohio.gov. The training shall remind all employees that complaints and all information submitted that identifies a complainant shall remain confidential pursuant to section 4729.23 of the Revised Code.

~~(K)~~(J) All policies and procedures maintained in accordance with paragraph (~~J~~I) of this rule shall be reviewed and updated on an annual basis.