Common Sense Initiative

Mike DeWine, *Governor*
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Comments on the proposed rules will be accepted until close of business on November 1, 2024. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Summer Reyburn

Regulation/Package Title (a general description of the rules' substantive content):

FYR 2024 Terminal Distributors of Dangerous Drugs

Rule Number(s): 4729:5-3-04, 4729:5-3-09, 4729:5-8-01, 4729:5-8-02, 4729:5-10-01, 4729:5-10-02, 4729:5-10-03, 4729:5-10-05, 4729:5-10-06, 4729:5-17-01, 4729:5-17-02, 4729:5-17-03, 4729:5-17-04, 4729:5-17-05

Date of Submission for CSI Review: 10/15/2024

Public Comment Period End Date: 11/1/2024

Rule Type/Number of Rules:

New/___ rules **No Change/__8__ rules (FYR? _Y_)**

Amended/__6__ rules (FYR? _Y_) **Rescinded/____ rules (FYR? ____)**

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

- 4729:5-3-04: Establishes the requirements for a terminal distributor to validate licensure (or licensure exemption) within the e-licensing system prior to conducting a sale or purchase. Fixes small grammatical errors and adds an exception for the sale or purchase to an EMS organization and an intercompany transfer if each location is properly licensed as a TDDD.
- 4729:5-3-09: Governs a pharmacy's ability to conduct occasional wholesale sales and permits a licensed terminal distributor of dangerous drugs to transfer or deliver dangerous drugs from one licensed location to another licensed location. Fixes small grammatical errors, adds definitions for dosage units and exempted transactions, and adds references to section 4729.54 of the Revised Code.
- 4729:5-8-01: Definition section for nonresident terminal distributors of dangerous drug rule chapter.
- 4729:5-8-02: Requires each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio to obtain a terminal distributor of dangerous drugs license. This includes any entity located outside of Ohio that ships, mails or delivers in any manner, dangerous drugs at retail into Ohio.
- 4729:5-10-01: Provides definitions that apply to Ohio's drug repository program.
- 4729:5-10-02: Establishes eligibility and notification requirements for pharmacies, hospitals or nonprofit clinics that elect to participate in a drug repository program.
- 4729:5-10-03: Establishes requirements for drug donation to a participating entity.
- 4729:5-10-05: Establishes eligibility requirements for individuals receiving donated drugs.
- 4729:5-10-06: Outlines required forms and record keeping requirements for the drug repository program.
- 4729:5-17-02: Establishes the requirements for terminal distributors of medical oxygen. Adds references to 4729.541 of the Revised Code and 4729:5 of the Administrative Code.
- 4729:5-17-03: Establishes the requirements for terminal distributors of nitrous oxide. Adds references to 4729.541 of the Revised Code and updates the requirements for maintaining records.

- 4729:5-17-04: Establishes the requirements for terminal or wholesale distributors of compressed medical gasses. Adds a reference to 4729.541 of the Revised Code.
- 4729:5-17-05: Establishes the requirements for terminal distributors of dialysis solutions. Corrects minor spelling errors.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   The proposed rules are authorized by sections 4729.26, 3719.28, and 3715.873 of the Ohio Revised Code.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   OAC 4729:5-3-09 implements a provision of federal law known as the Drug Quality and Security Act by adding the definition of an exempted transaction.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Except for OAC 4729:5-3-09, this rule package exceeds federal requirements because the regulation of dangerous drugs and the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio Board of Pharmacy.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**
   Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy.

   Section 3719.28 of the Ohio Revised Code authorizes the Board of pharmacy to adopt rules governing controlled substances. These rules are necessary to provide uniform standards for drug repository programs including what dangerous drugs can be accepted by the program and safeguards to prevent the diversion of such drugs.

   Section 3715.873 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules governing the drug repository program. Without these regulations, the Board would not be able to set uniform requirements for drug repository programs.

Section 4729.70 of the Ohio Revised Code requires the Board to adopt a medical gases safety program.

Without these regulations, the Ohio Board of Pharmacy would not be able to provide uniform standards for the distribution of dangerous drugs.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**
   The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.
   N/A.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   This rule package was distributed for initial public comment by posting the rule package to the Board's proposed rules website. Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**
    Stakeholders did not provide any comments on the proposed rules in this package.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

    Scientific data was not used to develop or review these rules.

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**
    Alternative regulations may include performance-based regulations, which define

the required outcome, but do not dictate the process the regulated stakeholders must use to comply.

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy and distribution of dangerous drugs, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another Ohio Board of Pharmacy regulation.

14. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

    Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and quarterly webinars from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community, and**
       Terminal distributors of dangerous drugs.
    b. **Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**
       The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a

representative business. Please include the source for your information/estimated impact.

- 4729:5-3-04 – The terminal distributor of dangerous drugs engaged in the occasional wholesale sale of dangerous drugs will be required to validate licensure using Ohio's eLicense system. The average time to confirm a licensed entity is approximately 1-2 minutes.
- 4729:5-3-09 – Governs a pharmacy's ability to conduct occasional wholesale sales. Also, permits a licensed terminal distributor of dangerous drugs to transfer or deliver dangerous drugs from one licensed location to another licensed location. Pharmacies conducting a sizable amount of occasional wholesale sales will incur costs of monitoring those sales to ensure that they are not exceeding the specified limits. Any pharmacies exceeding this limitation will have to obtain a wholesale distributor license.
- 4729:5-8-02 – Requires each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio to obtain a terminal distributor of dangerous drugs license. This includes any entity located outside of Ohio that ships, mails or delivers in any manner, dangerous drugs at retail into Ohio. Licensure as a terminal distributor of dangerous drugs costs between $160 and $220 annually. The application takes between 30-60 minutes to complete.
- 4729:5-10-02 – Establishes eligibility and notification requirements for pharmacies, hospitals or nonprofit clinics that elect to participate in a drug repository program. Adds notification requirements. The notification requirement will take approximately 5 minutes to complete and will be completed online.
- 4729:5-10-05 – Establishes eligibility requirements for individuals receiving donated drugs. Adds provisions allowing an individual who current resides in the state and an individual who is uninsured or underinsured to be eligible to receive donated drugs through the program. The adverse impact of this rule is the administrative costs of developing any additional eligibility requirements as permitted by the rule.
- 4729:5-10-06 – Outlines required forms and record keeping requirements for the drug repository program. Adds specific information that should be included on each donor form. Adds a requirement that donor and recipient forms should be maintained for at least three years (as is the current standard

for all pharmacy records). The adverse impact of this rule is the administrative costs of developing and maintaining donor forms.

- 4729:5-17-02 – Establishes the requirements for terminal distributors of medical oxygen. Licensure as a terminal distributor of dangerous drugs costs $160 annually. The application takes between 30-60 minutes to complete.
- 4729:5-17-03 – Establishes the requirements for terminal distributors of nitrous oxide. Licensure as a terminal distributor of dangerous drugs costs $160 annually. The application takes between 30-60 minutes to complete.
- 4729:5-17-04 – Establishes the requirements for terminal or wholesale distributors of compressed medical gasses. Licensure as a terminal distributor of dangerous drugs costs $160 annually. Licensure as a wholesale distributor of dangerous drugs costs $950 annually. Both applications take between 30-60 minutes to complete.
- 4729:5-17-05 – Establishes the requirements for terminal distributors of dialysis solutions. Licensure as a terminal distributor of dangerous drugs costs $160 annually. The application takes between 30-60 minutes to complete.

16. Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify. ***(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

- 4729:5-3-04 – Changes the requirements for licensure verification for EMS and intracompany transfers. This will save EMS, hospitals, and those conducting intracompany sales both time and administrative costs.
- 4729:5-3-09 – Allows local health departments to conduct occasional wholesale sales of dangerous drugs to other health departments. This will reduce costs for local health departments.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform standards for the practice of pharmacy or the preparation/distribution of dangerous drugs, including medical gases.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

This rule package does not provide any exemptions or alternative means of compliance for small businesses when it comes to the handling or destruction of controlled substance medications. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy or the preparation/distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff are available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

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 4729:5-3-09 | 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 4729:5-8-01 | 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 4729:5-10-01 | 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 4729:5-17-01 | 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. (AMEND)

(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 **or who are exempted from licensure in accordance with section 4729.541 of the Revised 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 accordance with the requirements of division 4729:5 of the Administrative Code.** ~~**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. (AMEND)

(A) ~~**Each person, located within this state whether located within or outside of this state, who conducts retail sales of medical oxygen nitrous oxide in this state shall obtain a limited category II terminal distributor of dangerous drugs license. 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.**~~

(A) Each person, whether located within or outside of this state, who conducts retail sales of nitrous oxide 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 **or who are exempted from licensure in accordance with section 4729.541 of the Revised Code**.

(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 accordance with the requirements of division 4729:5 of the Administrative Code.** ~~**in a tamper-evident manner to deter and detect unauthorized access.**~~

(D) All retail sellers of nitrous oxide shall maintain records of the purchase of nitrous oxide at wholesale and the sale of nitrous oxide 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.

~~**(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. (AMEND)

(A) Each person, whether located within or outside this state, who seeks to possess or sell compressed medical gases, **including medical oxygen and nitrous oxide,** 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~~ a** terminal distributor of dangerous drugs license in accordance with section 4729.54 of the Revised Code**, or are exempted in accordance with section 4729.541 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.